

Janssen's Martin  
Price on having  
open dialogue  
with HTAs

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Coronavirus' effect  
on drug pricing  
and reimbursement  
approvals

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# Market Access: Breaking Barriers

Plus: How COVID-19  
is changing pharma

Breaking barriers  
to patient access  
in rare oncology

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# Market Access: Breaking Barriers

It's hard to believe that the last issue of Deep Dive went out in a world without lockdowns, mass economic disruption and overloaded healthcare systems – but now the industry has been forced to make ten years' worth of changes in two months thanks to COVID-19.

In this special issue of Deep Dive we look at what the pandemic means for the industry's market access efforts – with insight from analyst Leela Barham and various speakers at this year's eyeforpharma virtual conferences – and also give some practical tips on how companies can accelerate the digital transformation necessitated by lockdowns.

But coronavirus is a drop in the ocean compared to the countless other diseases pharma is trying to tackle.

It's important that we don't forget about that during the current chaos, so pharmaphorum has assembled some of the industry's top experts to explore the market access challenges that will remain during and after the crisis – including access for biosimilars, how R&D processes affect reimbursement, and how pharma can work with payers to make sure as many patients as possible get access to drugs.

I hope you're all staying safe in these unpredictable times!

I hope you enjoy the issue.

Kind regards,



**George Underwood**  
Editor, Deep Dive, Market Access: Breaking Barriers

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**The Future of Oncology  
(June 2020)**

Plus:

- The biggest news from ASCO's virtual meeting
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# Janssen: 'Open dialogue' needed with HTAs to improve access

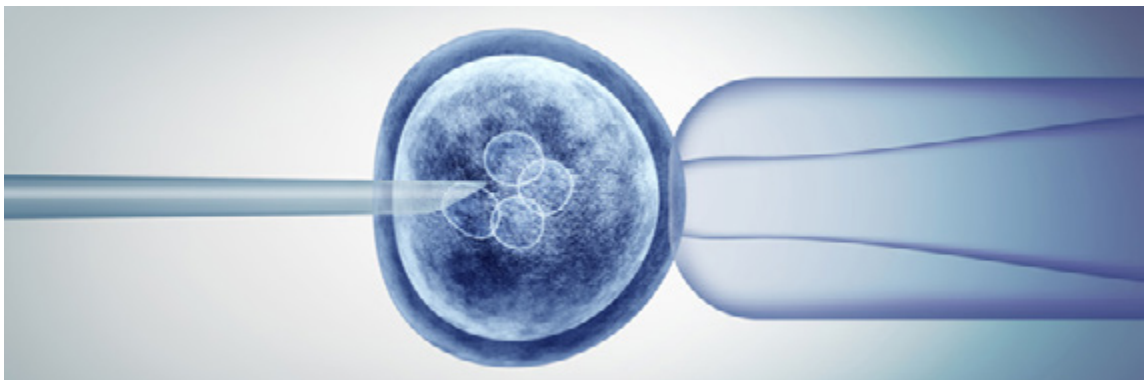
The world of life sciences is changing rapidly, and the traditional ways of assessing drugs may no longer be fit for purpose. Martin Price, vice president of health economics, market access and reimbursement in EMEA for the Janssen pharmaceutical companies of Johnson & Johnson, says that the only way forward is for pharma and HTA stakeholders to engage in open dialogue – and the company has started spearheading initiatives to achieve this.



Having worked in the NHS as a hospital pharmacist before moving into market access roles in the pharma industry, Price has seen many changes that have affected the HTA process – and this has only accelerated in recent years.

“The scientific advances we are making today, many of which would have been improbable just a few years ago, are incredible. But they also present challenges to market access.

“Cell and gene therapies involve a one-time dose, which raises questions about how you measure treatment success when it may take some time to observe the long-term benefits, especially in terms of overall survival.”





Some of these therapies, such as Yescarta and Kymriah, have been approved based on compelling efficacy data from relatively small non-randomised phase 2 studies – meaning there is some reticence from patients to enter into randomised controlled trials (RCTs) in a space where equipoise is quickly fading. From an HTA perspective however, the lack of randomised data together with the short-term overall survival data are two key factors that create uncertainty when it comes to appraisals of evidence.

“On top of that there can be an uneven cost structure – the cost is upfront but the benefits accrue over many years,” says Price. “The unique characteristics of cell and gene therapies require us to look differently at how we achieve timely market access.”

Like many others in the industry, Price is particularly interested in the potential of real-world evidence (RWE) to address these challenges – collecting data post-launch could enable innovative payment models, such as spreading payment over time for one-off treatment administration.

“Those of us who have been working in this area for a while have been looking at real-world evidence for a long time, but in the last few years its importance has grown tremendously. That is being driven by advances in both science and in digital technology.”



As RWE becomes more commonplace it will help facilitate the use of flexible payment models – for example those using iterative evidence generation over time, rather than making binary decisions about the likely value of a new treatment at a single point in time. This could be important for the growing number of personalised medicines likely to be launched on the basis of single-arm data.

Price says that Janssen is “investing heavily” in RWE, particularly in initiatives such as federated data networks, where the company is linking information from many different databases across several countries into a common data model.

An example of this is the company’s HONEUR (Haematology Outcomes Network in Europe) network, which now comprises 144 sites with information on more than 18,000 blood cancer patients.



HONEUR's goal is to enable participants to quickly scale and leverage RWE to answer questions in real time, which will accelerate research and improve conclusions by analysing treatment data from as many sources as possible.

"If we want to truly move towards a more value-based healthcare model where we track, monitor, measure and reward the delivery of outcomes in real-time, RWE is key," Price says.

He notes, however, that the acceptance of RWE is variable between different countries, and that more investment in and wider acceptance of this type of evidence is needed.

"There's certainly more we can do in that area. We're seeing a range of responses from HTA agencies across the EMEA region.

**"To be prepared for this new world and speed up decision-making, we need more flexibility with our payment models and we need to embrace different types of data."**

These alternate data approaches could also include different endpoints for innovative cancer therapies.

"In many HTA systems a lot of weight is put on showing an overall survival advantage as a means to demonstrate the clinical value of cancer treatments.

"As treatments start to have longer-term impacts, HTA agencies need to become more comfortable with making timely decisions on the basis of intermediate or surrogate endpoints, such as minimal residual disease (MRD) negativity in multiple myeloma."

Price is calling for more "open dialogue" between stakeholders on how the sector can address this new paradigm – where treatments are getting better, patients are living longer and, as a result, different kinds of data are emerging.



“A lot of these HTA processes were developed and set into place 15-20 years ago. The world has changed. Treatments are far more effective. We owe it to patients to make sure that we continue on that journey by modifying our processes.”

He says the best example of this is in HIV.

“When I started in the industry, the endpoint we used in HIV trials was overall survival. Today you wouldn’t dream of using that, because treatment advances mean many patients have a life expectancy that’s near-normal.

“We need to learn from that and evolve our decision-making in therapy areas such as cancer, and this needs to start with an understanding and recognition of the challenge we have ahead of us.”

## Future-proofing for HTA

In an attempt to future-proof against these potential HTA challenges, Janssen has set up an internal programme, Health Technology Assessment of innovation in Cancer (HTAiC), to work on potential solutions.



The programme has three objectives.

“The first is to establish a common understanding among different stakeholders and communicate why we need to reform HTA appraisal processes,” Price says.

“The second objective is to come up with solutions. It’s incumbent upon pharma to produce ideas on how we can evolve HTA methods so they continue to be fit for purpose.

“The third element is working with the external world to try and effect change. We believe that we need more opportunities for dialogue and collaboration among different stakeholders – everyone from patients and patient advocacy groups, to clinicians, payers, policy-makers and health economists – so we can drill down into which of the different options need to be implemented. We can’t be successful if pharma is the lone voice in all this.”



He says these options could include things like intermediate endpoints, risk-sharing payment models, or 'adaptive HTA', where after an initial decision the company commits to collecting additional data, perhaps through RWE, and the drug is reassessed further down the line.



"Patient access has to be at the centre of all this," says Price. "If stakeholders can recognise that HTA reform is needed to ensure access, then hopefully we will see increased collaboration to achieve that shared vision."

Price's main hope is for a more flexible approach to HTA in the future.

"At the moment, decision-making frameworks can be quite rigid. If you don't show certain endpoints immediately, the clinical rating by HTAs is often downgraded.

"Within oncology, we see different tumour types acting and responding in different ways. Perhaps we need to have alternate types of outcome measures depending on the specific cancer. That will enable us to make better decisions for patients earlier on."

He adds that one of his main frustrations is with the large amounts of variability across countries in how their systems work.

**"If we can all share the aim of trying  
to make the right decisions faster,  
perhaps we can address this."**

Price says that generally HTAs seem open to this kind of dialogue.

"Some newer technologies like CAR-T are causing them to look at these issues and think about how they can do things differently. Generally, regulators have been much more agile in how they assess the benefits of new treatments than payers have.

"If we could have more opportunities to talk under safe harbour conditions about some of these challenges, that would be of great benefit to everyone."

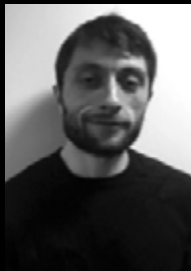


## About the interviewee



Martin Price is vice president of health economics, market access and reimbursement in Europe, Middle East and Africa at the Janssen Pharmaceutical Companies of Johnson & Johnson, a role he has held for the past six years. In this capacity, Martin leads the teams responsible for achieving optimal and accelerated market access, at a fair and value-based price, for Janssen's new products and indications. Prior to this, Martin worked in Janssen's UK affiliate, latterly as external affairs director, where he was responsible for Market Access, Communications and Government Affairs. Martin joined Janssen in 2001 from GlaxoSmithKline, where he began his career as senior health outcomes manager.

## About the author



George Underwood is a senior member of the pharmaphorum editorial team, having previously worked at PharmaTimes and prior to this at Pharmafocus. He is a trained journalist, with a degree from Bournemouth University and current specialisms that include R&D, digital and M&A.





# Market access in the time of COVID-19

COVID-19 has left no part of life untouched, including health technology assessment (HTA) and other payer agency activities, and it will likely have a lasting impact on market access. Leela Barham takes stock and looks ahead.

## Key points

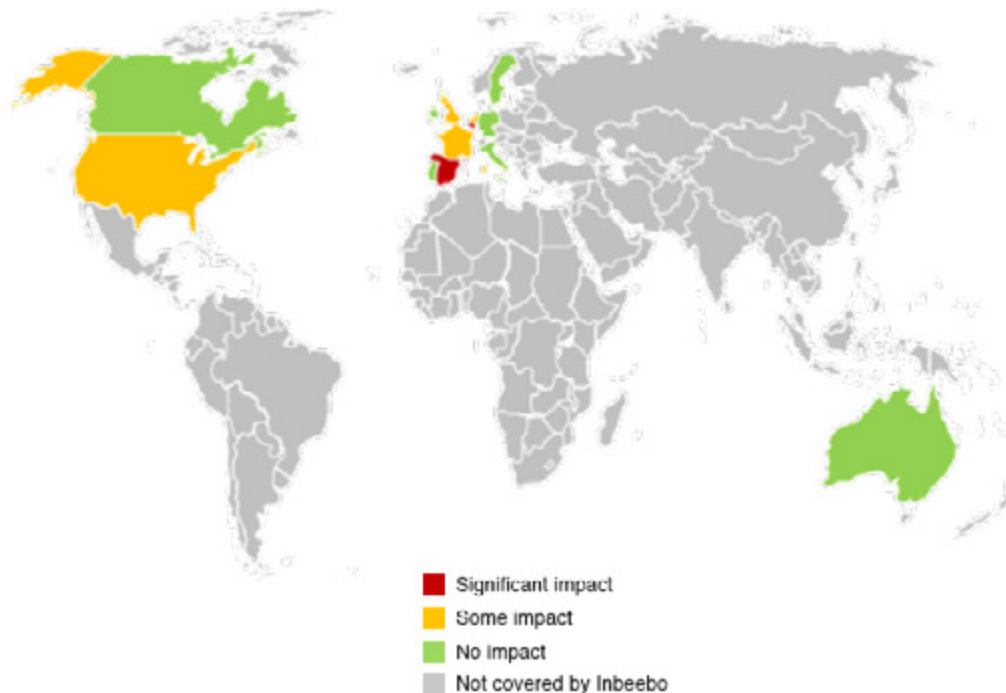
- Manufacturers should be aware of the potential for delays to drugs close to launch as HTA and payer agencies are prioritising and need more time to deliver their work while also delivering on their remits for COVID-19
- Delays could range from three months to longer if the drug is not considered a priority
- In the medium-term, pressure for companies to offer significant value for money will not abate as COVID-19 puts more and more strain on health care budgets
- A debate on what COVID-19 means for HTA, in terms of what is valuable and the willingness to pay for it, has already started and will continue potentially generating a stronger case for change in how HTA is practiced

## The short-term impact: delays and virtual working

COVID-19 has had an impact on many HTA and payer agencies. Inbeebo, a specialised market access consultancy, has been monitoring and mapping the impact on market access (see figure 1).



Figure 1: COVID-19 impact on market access



Source: Map based on data from Inbeebo, available at: <https://inbeebo.com/covid-19-impact-on-market-access/>. Situation as at 1 May 2020.

As illustrated in figure 1, the impact varies across the agencies. For the UK, the situation is a little more nuanced than implied by the map.

The Welsh based All Wales Medicines Strategy Group (AWMSG) took the decision to stop their appraisals altogether, allowing staff to focus on COVID-19, and cancelled three meetings. The committee is next due to meeting on the 16 June 2020.

The Scottish Medicines Consortium (SMC) cancelled meetings in March, April and May.

The National Institute for Health and Care Excellence (NICE) has taken the decision to prioritise what it can work on. As NICE has acknowledged itself, many of the committees that make the recommendations are frontline workers in the NHS. Hard to get them along to meetings at times like these, even if they're remote. Plus NICE staff are working hard producing COVID-19 guidelines.

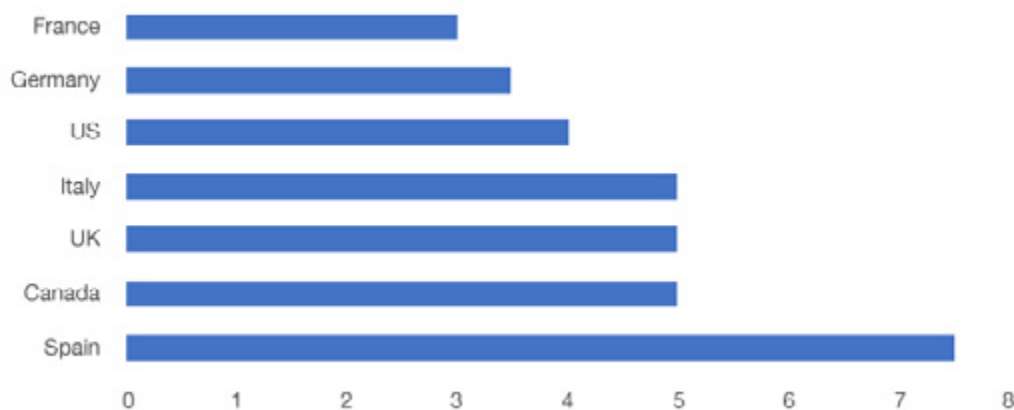
NICE, therefore, is focusing its Technology Appraisal (TA) work on what is classed as therapeutically critical. This includes all TAs on cancer treatments with the exception of reviews of those treatments that are in the Cancer Drugs Fund already. There are other treatments that NICE has deemed therapeutically critical; including, for example, Stelara (ustekinumab) for treating moderately to severely active ulcerative colitis and Trikafta (elexacaftor/tezacaftor/ivacaftor) fixed dose combination for treating cystic fibrosis with F508del mutation. The practical fallout is that NICE did not hold any TA committee meetings in April 2020.

Other European HTA agencies have had to look again at what can be delivered and identify priority work including the Institut national d'assurance maladie-invalidité (INAMI) in Belgium, Haute Autorité de Santé (HAS) in France and Zorginstituut Nederland (ZIN) in the Netherlands. The US-based Institute for Clinical Effectiveness Review (ICER) in the US has announced delays to its work too, although it plays a less clear-cut role in influencing pricing and reimbursement than its European counterparts.

While it will differ product by product, delays could range from three to 7.5 months according to a payer survey from ZS Associates (figure 2). The survey, conducted from 30 March to 7 April 2020, included 25 payers from the US, Canada, UK, Germany, France, Spain and Italy, with ten from the US.



Figure 2: Expected delay to timelines for pricing and reimbursement approval.



Source: Data from ZS Associates. (2020). COVID-19 Payer Pulse.

Then there are those agencies that are confident that they can continue their work without delays. The Canadian Agency for Drugs and Therapeutics (CADTH) is one of those. The agency has asked stakeholders – companies and patients – to get into contact if they face difficulties in light of COVID-19. In Canada, pricing comes under the pan-Canadian Pharmaceutical Alliance, and they have put some negotiations on hold. This explains the view that there is no impact – as CADTH carries on – in the map, but with delays for market access expected by payers in Canada.

COVID-19 has led to changes in the way that agencies work. Video conferencing is the go-to way to get things done. NICE will be running TA committee meetings in May via Zoom and has already run two virtual committee meetings in March. The Italian Medicines Agency (AIFA), Germany's Gemeinsamer Bundesausschuss (G-BA), Australia's Pharmaceutical Benefits Advisory Committee (PBAC) and HAS are also using virtual meetings.

IQVIA's 27 April 2020 update on COVID-19 in the EU5 markets suggests that 8 product launches have been delayed, disrupted or otherwise impacted by COVID-19. But they acknowledge that this is likely to be an underestimate of the true impact.

## The medium-term impact: delays to wider work



For NICE, it's not just the current TAs that are affected by COVID-19. The body is also currently reviewing its methods and processes, and the timeline for that has had to change in light of COVID-19. The review will now be working to go to a six-week consultation on the evidence and considerations for change in October and November 2020, with further consultation in February and March 2021 and implementation slated for June 2021 onwards.



In France, there were already extensions put in place to negotiate a pricing framework between the Economic Committee of Health Products Comité Économique des Produits de Santé (CEPS) and the pharmaceutical companies association Les Entreprises du Médicament (LEEM). The timelines for this could be extended beyond the pencilled-in end date of July 2020.

CADTH and Ireland's National Centre for Pharmacoeconomics (NCPE) have both cancelled their setpiece conferences that would usually be run every year.

## The long-term impact: higher expectations from payers? Future changes to HTA?

While it's difficult to know the full cost of treating COVID-19, as well as the cost of the range of government packages from funding for vaccine development to try to mitigate the economic fallout, it is clear that funding for health will become ever tighter. The payers surveyed by ZS Associates expect budgets to be cut by 15 to 25%.

Companies were already hard pushed to show the value of their treatments, and there is going to be no let up on this. Not only will payers want better deals, working virtually could become the new normal. Companies are going to have become adept at influencing via video call, in addition to needing to produce iron-clad value propositions in their written submissions.

HTA may itself need to change in light of COVID-19. There has always been a healthy debate on HTA, not least about whether the way it's practiced – with many agencies focused on the cost per Quality Adjusted Life Year (QALY) – means that it captures what is important to patients, clinicians, health care systems and society at large. Many have been pushing for change when it comes to HTA for some time.



A Special Task Force at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has looked at whether HTA should be expanded to bring in other elements that are either not systematically looked at – such as productivity – or novel elements. These novel elements include fear and risk of contagion, which seem to be particularly relevant now. They appear to have motivated countries around the globe to take the measures that they have, including putting together packages to support the economy. The value of hope too must play a role in the public resources being put in to develop a vaccine, as well as explore which treatments that are currently available that might help to manage COVID-19.



Rarely has cost-effectiveness been a part of the analyses considered to inform responses to COVID-19, according to researchers in a blog published by the Center for Global Development. That means that there is a disconnect between health economic considerations as they apply to a whole of health interventions in 'normal times' that don't apply in a pandemic. There are already those who question whether this is right, or wrong, which hinges on how far you want to make COVID-19 a special case.

It's also not yet clear just how HTA will be applied when it comes to treatments for COVID-19. There are already signs that the approach is changing. For example, ICER has put forward two models for pricing of Gilead's Remdesivir (an investigational nucleotide analog with broad spectrum antiviral activity) when used for treating COVID-19. Their first is based on cost-recovery, the second using cost-effectiveness thresholds. The difference is stark; \$10 and a ceiling of \$4,500.

Even more uncertain is how HTA will consider future vaccines; yet it is in vaccines where there has been controversy – for example, a threshold of £15,000 per QALY has been mooted for England, far lower than the standard range of £20,000 to £30,000, let alone those that apply for treatments for really rare conditions which can go over £100,000 per QALY.

While this is a debate that will shape future decisions when (hopefully) a vaccine comes for COVID-19, it is also a debate about just what our current thresholds for cost-effectiveness are based on and whether or not they are right. This is because while it's hard to pin down a number that anyone will agree on, it's likely that the cost per QALYs for countries' pandemic responses is likely to be very different – far higher – than those thresholds normally applied. Does that mean we need to look again at what is valuable and what we should be willing to pay for it?

## About the author



Leela Barham is a researcher and writer on health and pharmaceuticals, from a health and policy perspective. Leela has worked with all stakeholders across the health care system, both in the UK and internationally, working on the economics of the pharmaceutical industry. Leela worked as an advisor to the Department of Health and Social Care on the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS).



A close-up photograph of a hand holding a smartphone. The background is heavily blurred, showing colorful bokeh lights in shades of orange, yellow, and blue. The hand is positioned in the upper right, with fingers slightly curled around the device. The smartphone screen is visible in the lower right, showing some indistinct content.

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# Breaking policy and perceptual barriers: Biosimilars

Experts from Research Partnership analyse the company's Therapy Watch data to identify how market access policy has impacted the adoption of biosimilars. We ask – what strategies should manufacturers of both biosimilars and originator biologics consider to optimise their brand's success?

Biologics are big business in Rheumatoid Arthritis (RA), with the first wave of TNF inhibitors Remicade (infliximab), Enbrel (etanercept) and Humira (adalimumab) all having achieved blockbuster sales since their launches in the early 2000s.

In recent years, as patents started to expire, an increasing number of branded and generic pharmaceutical companies have launched biosimilars, offering meaningful discounts relative to the originators – an appealing proposition for strained healthcare systems under pressure to contain costs.

Leveraging over two years of syndicated RA Therapy Watch data\* from September 2017-December 2019 in France, Germany, UK, Italy, and Spain, we looked into what parallels could be drawn between country trends in biosimilar prescribing and individual market policies designed to promote their use.

Linking the implementation of policies to changes in the prescribing reality allowed us to compare the effectiveness of different policy instruments at achieving their objectives of realising the potential cost-savings associated with the prescribing of biosimilars over originators.

This leads us to consider what strategies originator manufacturers can employ to break the policy barriers to ensure continued patient access to their branded biologics, and what biosimilar manufacturers can do to break the perceptual barriers to switching to their (potentially) more cost-effective products.

*\* Therapy Watch is a 'real-time' syndicated market tracking tool that provides market researchers, marketing teams and brand managers with strategic and tactical market information using patient record forms*





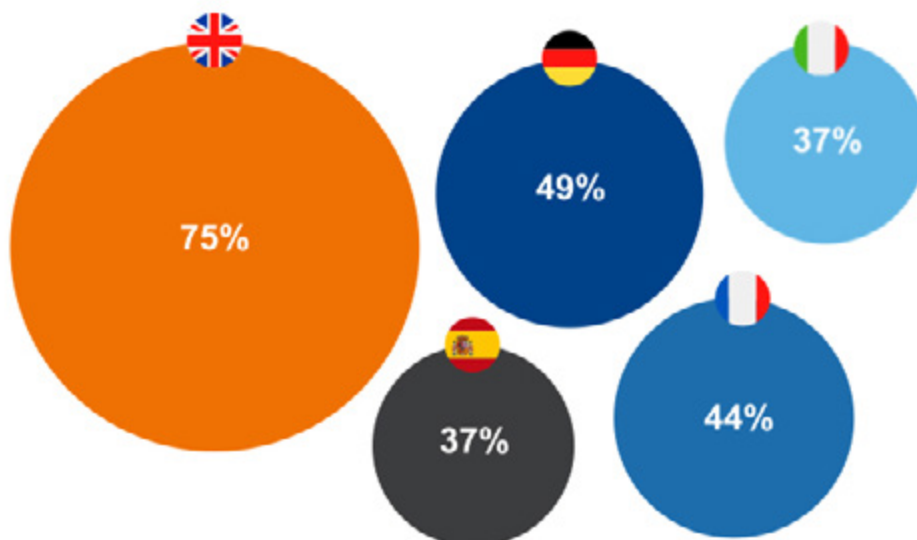
## EU5 comparison

A recent snapshot of Therapy Watch data shows the proportion of biosimilar prescriptions in RA based on an aggregation of molecules which have biosimilars currently available. The wide range in penetration of biosimilars across countries is clear. As we delve into the policy context in each market, we can explain these country variations by the uneven application of tools used to encourage biosimilar prescribing.



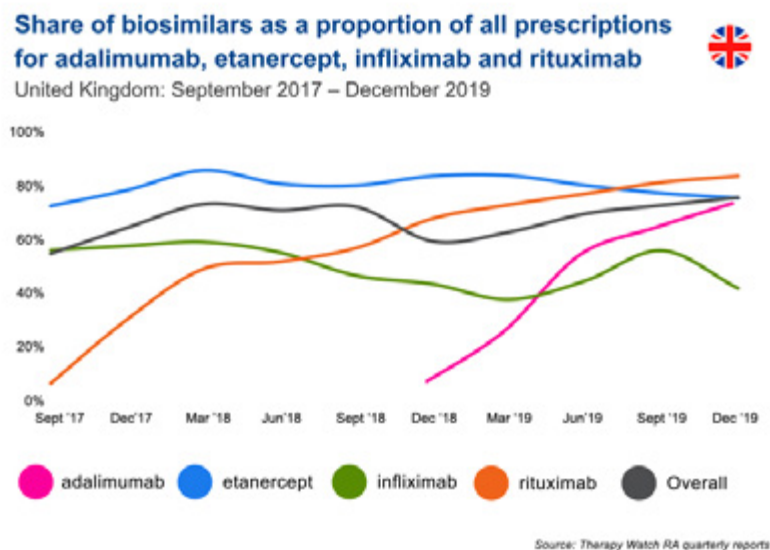
### Share of biosimilars as a proportion of all prescriptions for adalimumab, etanercept, infliximab and rituximab

December 2019



## United Kingdom

The UK has the highest rate of biosimilar adoption. In September 2017, biosimilars already made up over 50% of the share of molecules that had biosimilars available, and their penetration has continued to rise.



Therapy Watch data also provides evidence of switching to biosimilars taking place in practice, with 27% of all UK treatment changes in Q3 2019 being within molecule (i.e. originator to biosimilar, biosimilar to biosimilar, or biosimilar to originator), the highest proportion in the EU5 (France second at 9%).

Despite the UK requiring biologics and biosimilars to be prescribed by brand name, allowing no possibility of automatic substitution at the pharmacy level, multiple policy levers are being employed that can account for this high uptake of biosimilars. First is the NICE recommendation to start treatment with the most cost-effective option – typically a biosimilar. Switching from an originator to a biosimilar is recommended on a case-by-case basis, although there have been pilot projects to enforce controlled switching to biosimilars.

NHS England also aims to incentivise biosimilar uptake through the Commissioning for Quality and Innovation scheme (GE3 Hospital Medicine Optimisation). Providers who adopt “best value” biologic products in 90% of new patients within three months of guidance becoming available, and in 80% of existing patients within one year, receive a bonus of 1% of the contract value for tariff-excluded high-cost drugs.

Procurement is via four regional tenders in England, plus country-level tenders in each of Scotland, Wales and Northern Ireland. Within England, local Clinical Commissioning Groups (CCGs) and hospital Trusts then make joint decisions on which products to prescribe. At this level, there are gain-sharing agreements designed to reward economical prescribing by allowing providers to keep a percentage of the cost savings achieved. Savings are split between the CCG who funds the drug and the Trust that prescribed them.

In parallel, work is being done to break the perceptual barriers to prescribing biologics, with NHS England working on an educational programme to improve confidence and understanding when it comes to appropriate use of biosimilars. The British Society for Rheumatology has also published guidance supporting the managed introduction of biosimilars.



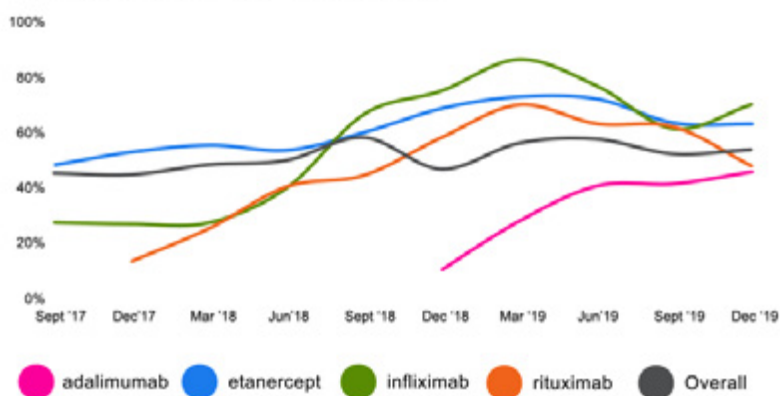
## Germany

Data for Germany shows an initial increase followed by a recent plateau in the prescription of biosimilars. As in the UK, biosimilars are exempt from INN (International Nonproprietary Name) prescribing and automatic substitution, but German statutory health insurers and regional physician associations (Kassenärztliche Vereinigung – KV) have also invested in physician education and implemented quotas. The level of quotas varies between KV, and local administrators can set additional targets, leading to regional variation in biosimilar penetration.



### Share of biosimilars as a proportion of all prescriptions for adalimumab, etanercept, infliximab and rituximab

Germany: September 2017 – December 2019



Source: Therapy Watch RA quarterly reports

Germany is the best example of applying a 'carrot-and-stick' approach to drive uptake. On the 'carrot' side, gain-sharing agreements have been implemented by the KV, with physicians who achieve set biosimilar quotas being allowed to bill additional services to their patients. On the 'stick' side, prescription patterns are monitored, with penalties for exceeding budget limits at the clinic level. Physicians who exceed their budgets by 125% need to pay the amount in excess of 115% unless they provide justification, further incentivising biologic prescribing as part of a drive to reduce overall spending.

Given the range of measures to promote biosimilar prescribing through both payer policies and physician education, why the plateau in uptake? Strong price competition from originators, through rebate contracts and tenders, may account for some of their continued market share. In reflection of increased price competition from originators, in February 2020, the Federal Joint Committee (G-BA) amended the positioning of their biosimilars policy to say that the physician should correspond to an economic prescription by adjusting the patient to 'an inexpensive product' (whether originator or biosimilar). The previous recommendation was simply to prescribe a biosimilar under the assumption the price would be lower.

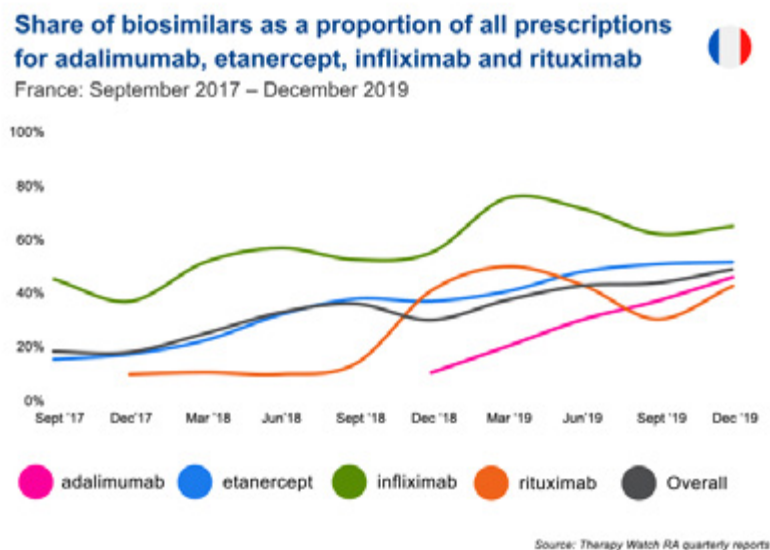
However, price competition from originators cannot fully explain biosimilars' plateauing performance; the low rate of in-molecule switching we see (only 3% of all treatment switches) is indicative of lingering hesitancy to prescribe biosimilars, suggesting perceptual barriers remain.

Recognising more had to be done, the G-BA proposed a law in 2018 that would allow automatic substitution of originators with biosimilars by pharmacists. This controversial law currently only applies to 'bio-identicals' (e.g. Inflectra and Remsima) but will be reviewed in 2022 and could potentially expand to all biologics.



## France

We see a slow trajectory of biosimilar uptake in France when reviewing historic data. This is despite a ministerial framework having been issued in 2017 to promote use of biosimilars including instructions for 70% of outpatient prescriptions to be for biologics.



A small but notable exception to this is infliximab biosimilars, which are more established as a proportion of infliximab use compared to other molecules, despite infliximab being less commonly used in RA overall.

The higher uptake of biosimilar infliximab than etanercept and adalimumab biosimilars could potentially be explained by Remicade being less promoted in the market compared to the other molecules, or their different routes of administration. Infliximab is a hospital product due to its intravenous administration, while etanercept and adalimumab are administered subcutaneously and therefore primarily used in a retail setting.

In the hospital setting, physicians' prescribing decisions are dependent on what is listed on their hospital formulary. Gain-sharing agreements in place between hospitals and social security encourage the awarding of single-winner tenders to lowest price offers, which can encourage the use of biosimilars.

Given these enforced discounts, and the fact that France is the sole country within the EU5 that allows automatic substitution of biosimilars at the pharmacy level, the low uptake of biosimilars in the retail setting might seem initially surprising. However, there is no incentive for pharmacists to switch. Therefore, despite encouragement and a supportive legal framework, automatic substitution is not being done in practice in RA. With physicians lacking confidence in biosimilars, pharmacists feel uncomfortable with making the switch as the physician is ultimately responsible for anything that may go wrong.

The variation between biosimilar uptake in hospital and retail settings in France provides a stark illustration that where physicians have the freedom to decide between originator and biosimilar, discounts alone will not be sufficient to achieve the desired levels of uptake of biosimilars. As in Germany, perceptual barriers to their prescribing still need to be broken. Meanwhile, originator manufacturers are doing all they can to prolong uncertainty in order to defend their market share.



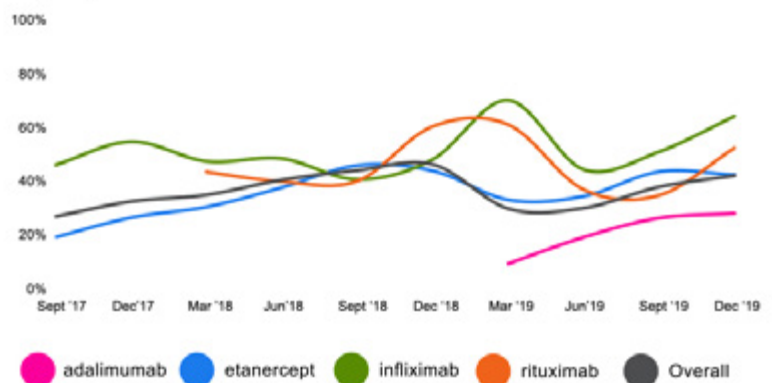
## Italy and Spain

We've considered these countries together given their similarly low and sluggish uptake of biosimilars in RA. Across both markets, only just over a third of RA patients who would be eligible for a biosimilar were actually prescribed one. This is despite expected net-level discounts at launch between originator and biosimilar of a minimum of 20% in Italy and around 25-30% in Spain.



### Share of biosimilars as a proportion of all prescriptions for adalimumab, etanercept, infliximab and rituximab

Italy: September 2017 – December 2019



Source: Therapy Watch RA quarterly reports

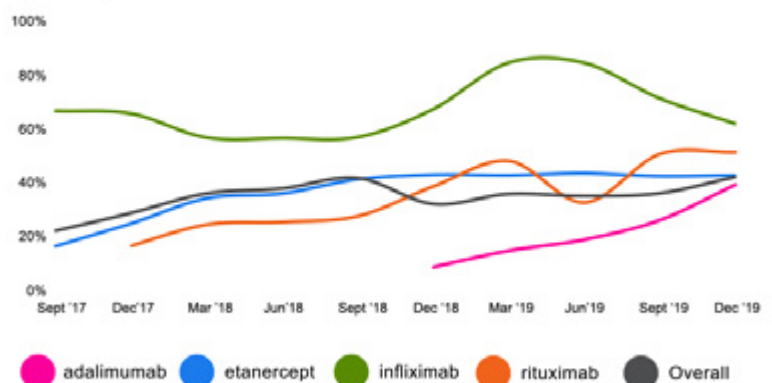
The simple explanation is that fewer policies to encourage biosimilar uptake have been implemented. Neither country allows automatic substitution for biosimilars, with no sign this will be permitted in the near future.

The Italian Medicines Agency (AIFA) issued a position paper in April 2018 recommending biosimilars for both treatment naive patients and those patients already treated with an originator biologic for economic reasons. However, its publication has not yet translated into any notable change in the data.



### Share of biosimilars as a proportion of all prescriptions for adalimumab, etanercept, infliximab and rituximab

Spain: September 2017 – December 2019



Source: Therapy Watch RA quarterly reports

In Spain, the use of biosimilars in new patients is encouraged but switching is not. The ultimate decision is at physicians' discretion, with the patient needing to consent to any switch. Our data supports the lack of switching to biosimilars taking place in practice, with only 3% of all treatment changes being within molecule.

Compared to other markets, we see more oscillation in the uptake of biosimilars between waves in both countries. The drops are potentially attributable to variation in the discount levels between originator and biosimilar and changes in which manufacturers are awarded the tenders.

Both healthcare systems are highly regionalised, so regional policies are contributing to variation in uptake of biosimilars at a level not shown in the country-level data. Tuscany, for example, set up a tender for infliximab that was won by the biosimilar, Inflectra, with physicians wishing to prescribe the originator Remicade needing to complete a specific form. Some regions have also set biosimilar quotas, but this varies between molecules and regions, and quotas are not binding or strongly enforced.

In Spain, approaches have been introduced in the Madrid region to try and improve uptake of biosimilars since 2010, with specific targets to increase the percentage of new patients on infliximab biosimilars included in 2016.

Momentum to push for stricter policies to encourage biosimilar uptake declined in recent years, with evidence of originators offering price parity with biosimilars. However, in late 2019, the Ministry of Health proposed an action plan to promote use of generics and biosimilars, including fixing lower prices vs. originators and allowing automatic substitution at the pharmacy level. Industry stakeholders have (unsurprisingly) raised strong objections and the current climate of political instability may delay or prevent approval – especially given the broader healthcare challenges Spain faces.

## Conclusion

The variation in biosimilar penetration demonstrates that lower price alone is not sufficient to drive high uptake, particularly in patients initiated onto an originator. In general RA treatment terms, physicians resist switching for non-clinical reasons. Patients tend to remain on treatments for years and are generally cautious about switching because if the efficacy is good, they do not want to risk switching. Prescribers' ongoing resistance to biosimilars is evidenced most strongly by German physicians' reluctance to prescribe them despite facing potential financial penalties for exceeding their budget.

Strong messaging from originator manufacturers when biosimilars first became available has likely contributed to this hesitation, as marketing teams strived to break the policy barriers to continued prescribing of their products. Company size and budgets are a relevant factor here, with originator companies having put much more money behind marketing than biosimilar manufacturers, which tend to be smaller.

Originators' efforts have been less successful in the UK, where a longstanding culture of communicating the value of cost savings to the NHS more broadly means physicians tend to be conscious about economic prescribing. However, we still see some resistance to biosimilar use, with higher-priced originators still being used, even here and in the French hospital setting where physicians have to circumvent tenders or miss out on savings for their hospital to continue prescribing them.

Countries with the highest biosimilar use (UK, Germany and France), all have some form of gain-sharing agreement in place. While there are multiple factors contributing to uptake, this could suggest that such agreements have at least some impact in motivating prescribers to use biosimilars, by allowing their practice or hospital to realise some of the associated cost savings.

That said, only legally-enforced automatic substitution at the pharmacy would be able to achieve the most economical prescribing outcomes – but this remains unpalatable across the EU5. It will be interesting to see how the proposed laws in Germany and the draft action plan in Spain develop.





# Looking forwards

As the RA market continues to shift away from these molecules towards JAK inhibitors, we are also seeing originator manufacturers increasingly deprioritising their focus on defending their share or being more prepared to compete with biosimilars on cost in order to win tenders. This is likely the case for those originator manufacturers who also have a JAK inhibitor in their portfolio, as they are instead focused on promoting the potential broader health economic savings that can result from their oral administration e.g. less need for nurses and training.

Despite waning competition from originators, it is clear from our data that the perceptual barriers to prescribing biosimilars will continue to be hard to break, especially when it comes to switching patients. In the absence of stricter policy controls, biosimilar manufacturers need to do more to reassure on quality and supply, as well as communicate the positive experience built up since they first became available – as long-term real world experience is the only thing that will fully address some physicians' uncertainty about interchangeability.

## About the authors



### **Rachel Howard**

#### *Director, Market Access*

Rachel is currently based in London, having previously lived and worked in the US and Asia. With over 10 years' experience in pharmaceutical market research, Rachel has extensive experience managing large scale, complex studies, both qualitative and quantitative, with a recent focus on market access and pricing research, including with payers. Rachel's experience covers many therapy areas, including Rheumatoid Arthritis.



### **Brett Gardiner**

#### *Director, Market Access*

Brett heads up Research Partnership's specialist market access team. He has managed and contributed to the development of pricing and reimbursement strategies for pharmaceuticals and medical devices in all stages of the product life-cycle across all major European markets, US, Japan, Canada as well as many emerging markets.



### **Julia Godfrey,**

#### *Research director, Therapy Watch*

Julia has 20 years of experience in healthcare research working in RP's syndicated division for the last 5 years. Julia's research experience spans all markets and many different therapy areas; however she brings particular expertise in Rheumatology.



### **Richa Munjal**

#### *Associate director, Therapy Watch*

Richa has over 10 years of experience in healthcare and pharmaceutical market research. She has worked on a variety of syndicated and adhoc projects across various therapy areas in all markets. Her areas of expertise include Rheumatology and Hyperlipidaemia.

## About Research Partnership

Research Partnership is the largest independent healthcare market research and consulting agency in the world. We collaborate with clients from the global pharmaceutical, medtech and biotech industries, providing research intelligence and strategic recommendations that elevate healthcare brands and power their success. Our specialist market access service supports the world's leading manufacturers in market access, pricing, and reimbursement.

To find out more please visit [researchpartnership.com/marketaccess](https://researchpartnership.com/marketaccess)

## About Therapy Watch

Established over 10 years ago, Therapy Watch is a 'real-time' syndicated market tracking tool that provides market researchers, marketing teams and brand managers with strategic and tactical market information using patient record forms (PRFs).

To find out more please visit [researchpartnership.com/therapywatch](https://researchpartnership.com/therapywatch)





## A novel approach to detecting Alzheimer's early

The grey matter in the brain may hold vital clues for early, accurate detection in Alzheimer's, and potentially also help pharma to find new drug treatments.

Oxford University spinout Oxford Brain Diagnostics Ltd is hoping to unlock some of these clues by introducing a new test that can spot the signs of dementia as early as possible, allowing for earlier intervention and better clinical research.

"The signs and symptoms of dementia are very subtle in the earlier stages," says Dr Steven Chance, the company's co-founder and CEO. "We need more accurate and better biomarkers both for drug development and to help clinicians make the right decisions earlier in the process for patients and their families."

Advanced clinical diagnosis methods have usually focused on measuring the build-up of amyloid plaques and/or tau tangles, which represent the main hypothesis about what actually causes Alzheimer's disease.







Examining the neuronal networks in the grey matter during the early stages of dementia symptoms has the potential to provide microscopic insights into neurodegeneration. OBD's method – CDM (Cortical Disarray Measurement) focuses on measuring the subtle micro-anatomical changes that are happening in the brains' cortex by using MRI with Diffusion Tensor images.

This novel approach was born of Chance's research into neuropathology, where he analysed brain samples through a microscope.

"Over the last decade, I found that a consistent issue in all the analyses was the changes that were happening in the brain with age. These findings guided me towards Alzheimer's disease where I discovered that cortical disarray could potentially shed a light on the diagnosis of the disease condition. I realised that the insight we can gain by looking at the brain through the microscope was not really being used in clinical practice with living dementia patients, because there's no way to get access to that information in life.

***"We wanted to create a method that delivered In-Life Pathology for patients."***

OBD can extract the data from MRI scans of the brain in living subjects.

"We originally scanned human brains, then compared the exact same part of the brain directly through the microscope, looking at a series of detailed anatomical measurements in order to compare the histology directly with the MRI data," explains Chance. "That enabled us to begin interpreting the measurements we're making."

This method is much more sensitive to subtle effects, which can aid early prediction, differential diagnosis and testing new drugs.

Importantly, it also circumvents debate over whether the amyloid hypothesis is correct, or whether to use amyloid or tau as a biomarker.

"Whatever hypothesis you have about the mechanism of Alzheimer's disease, they all converge on the neurodegeneration in the brain," says Chance.





This approach can also apply to other neurological diseases like multiple sclerosis or schizophrenia, and Chance says the company is interested in exploring those spaces as well.

He says that OBD's goal is to become the gold standard for measuring neurodegeneration in dementia.

"Pharmaceutical companies are facing all sorts of challenges. In the last two decades there have been hundreds of trials that have failed to produce any new disease-altering drugs for Alzheimer's.

"We can help drug companies improve their discovery process by enriching their patient cohorts and making sure that they get the right individuals in the trials.

"We can also enable them to measure the benefits of their drugs at that subtle microscopic level, and improve their classification of disease for stratifying patients to make sure the right people receive the right treatments."

## About the interviewee



Dr Steven Chance is the CEO and co-founder of Oxford Brain Diagnostics. Previously he was associate professor in neuroscience at the University of Oxford, with 20 years' experience researching the microscopic basis of brain disease, particularly Alzheimer's disease.

## About Oxford Brain Diagnostics

Oxford Brain Diagnostics, a spinout company from the University of Oxford, has been launched to bring to market a new approach for early detection of changes associated with Alzheimer's disease from MRI brain scans. Oxford Brain Diagnostics are developing a clinical diagnostic platform that will use CDM measurements generated from a patent protected software-based analysis created by the company's two co-founders: Dr Steven Chance (CEO and formerly at University of Oxford) and Professor Mark Jenkinson, University of Oxford.

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# 6 ways to digitise your business at pace

As the COVID-19 pandemic stretches on, can your business survive without face-to-face customer contact? For decades, I have seen healthcare and pharma companies prioritise face to face contact over digital channels – now is the time to realise the multi-channel opportunity.

March and April 2020 have delivered extraordinary challenges to business owners and workforces globally thanks to the COVID-19 outbreak and the resulting lockdowns across the world. Leaders have been asked to make complex daily decisions to keep employees, customers, and communities safe, while also ensuring they protect jobs and keep businesses moving forwards.

Healthcare and pharma companies who have historically favoured face-to-face (F2F) contact (rep visits to physicians, congresses, and events) have faced, almost overnight, the removal of these core tactics. The challenge to deliver business-as-usual without these long-standing, relied-upon tactics is unprecedented. But what if the toolkit for delivering business-as-usual were more multichannel?





Customers have already moved to a multichannel approach. Patients, KOLs, physicians intuitively seek information they need via digital channels and in general run their lives in a multichannel way.

Our customers are also just people. They expect communications from pharma and healthcare organisations to be delivered in the same intuitive way that they shop online for groceries, book their holidays, or buy insurance. Brands are expected to deliver content that is personalised, timely, useful, and relevant. Websites need to answer customer needs and be simple to navigate. Tools and apps must offer services to aid simpler, better outcomes and disease support.

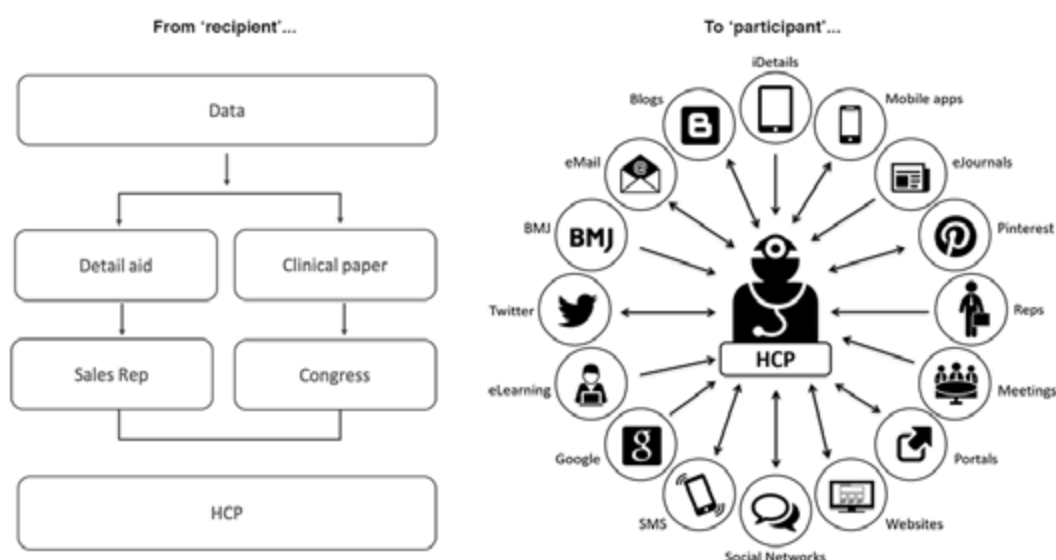
Industries outside pharma and healthcare have adapted to a multichannel approach too, removing the reliance on F2F. A tangible example of this is the financial services sector (specifically banking). The sector has seen a huge online switch with 73% of consumers globally opting to use an online banking channel at least once every 30 days<sup>1</sup>, carrying out banking tasks on their mobile devices, through social and many other digital touchpoints. While the adjustment may be less significant, I am certainly seeing change in the pharma industry – but there is lots more that companies can do to provide innovative ways to serve their increasingly digital native physician and patient population.

In these difficult times, initial responses are to provision staff with digital tools that enable remote working and collaboration. However, beyond this unprecedented period, how do you build up business resilience to deliver more engaged customers, more opportunity for success, build in business efficiencies globally, all whilst fostering more connected and empowered teams?

Tools, technology, multi-channel frameworks and best practices are available, not just for now, but to support the future ways we work. How? Here I outline six practical, quick wins, to 'get digitally fit' and develop a multi-channel approach at pace for long-term growth.

## 1. Enable your field force for remote engagement

How do you enable your field force and ensure they can maintain a level of customer engagement at these challenging times for their customers?



Proactive sales meetings at this time will no longer be appropriate, given the critical roles customers are playing in the fight against COVID-19, however pharma should still be on point to respond to the professional questions and needs of HCPs. Upskill field-based reps with remote meeting software so that reps can reactively respond to customers' requests at the point of need. Rep-led email solutions can also prove invaluable connection points for sharing content needed by HCPs.

Brands also need to consider how they evolve their strategies to support changing customer needs, firmly putting customer centricity at the heart of any approach. Customers should become participants rather than recipients, meaning reps and supporting teams (marketing, leadership, brand/product) need to think differently, ensuring they are supporting and serving customers rather than simply sharing promotional or product content.

## 2. When a symposium becomes a webinar

Congress cancelled? Do you have important scientific evidence you want to share with your customers?



Webinars may provide an interim solution and can take several forms, including presentations, workshops, lectures, or seminars. Customers confirm that they prefer to access online webinar content in an 'on demand' format so it is important, especially now, that HCPs can consume content when they choose to do so, via personalised email links for consenting HCPs or via credible company websites.

Consider leveraging this channel to share new science related to your products or disease areas including study designs, efficacy and safety data and breaking news and remember that, especially at the moment, customers are most likely to spend the time only if the content adds incremental value to their roles and enables and supports them professionally.



### 3. Keep in touch (email)

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We are aware of the importance of email for us and our customers professionally. Now more than ever this need is polarised by email's ability to reach customers at their point of need, via a channel they use throughout their working day.



If pharma uses email appropriately – i.e. linking to the resources, webinars, remote calls, and content they need to serve customers – this can be a quick and trusted way to reach HCPs. However, brand marketers must think carefully around tactics for email design and creation, considerably reducing the frequency sent and actively pulling back on email for those physicians we know will be at the front-line of the fight against COVID-19. In turn, creation of tailored content, served via rep channels or appropriate and relevant newsletter content can still provide value for HCPs in other specialities if done well. Email can lead customers to useful company owned resources for future content needs, adding value and helping them serve their patients more effectively.



## 4. Get your house in order and get visible (websites and search)

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What content can you make available via the channels that have most impact and reach with your customers? Customers without time for meetings will still be using websites to answer their clinical questions.



Owned brand, educational and patient focused websites are a great way to support HCPs – a one-stop-shop for all content, services, and support. For physicians, as for everyone else in the world, search is the number one go-to channel. Do not underestimate the power of having your content available to them. 99% of physicians use search engines (primarily Google in Europe) to find information about drug products, 90% of them at least weekly.

## 5. Join the social conversation

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Do not be afraid to embrace digital channels that previously might have been 'nice to have' rather than essential parts of your marketing mix. In a rapidly changing environment, channels like Twitter have become essential for many HCPs to keep on top of the latest news.



Consider how you can encourage confidence in social channels, especially professional groups where HCPs can connect with peers or KOLs. Can you help HCPs support their patients by providing high-quality content for patient groups to share in their social spaces, especially Facebook and YouTube, at a time when access to healthcare services might be restricted?

Develop your social listening strategies to understand the narrative around your therapy areas and brands, in order to help develop a content strategy to answer customers' questions and concerns. This content, or signposts to it, can be distributed in social channels as well as on your own website.

## 6. Change management: digital training

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While acknowledging that technology and channels referenced here represent a tangible opportunity for pharma to reinvent the way it engages customers and maintains brand loyalty, success is tied inextricably to the ability to embed long term change. To foster change, strong leadership empowered by digital expertise is required.



Ultimately it is critical to not just 'stand-up' a new technology or digital channel but also ensure ongoing, in market support and training – especially as learnings, channel insights and experience evolves.

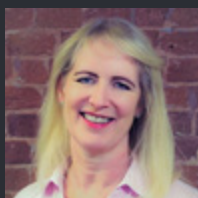
While face-to-face training sessions may not be available, teams can connect via eLearning modules, and customised channel-focused webinars to improve capability, inspire change and outline best practice. Follow these up with playbooks and on-the-job 'how-to' guides. Appoint digital ambassadors and subject matter experts who can share expertise, give encouragement to and mentor peers, supporting ongoing excellence.

***If you found this article of interest or want to know more about the quick wins to 'get digitally fit' and develop a multi-channel approach at pace come join our webinars starting Tuesday 2 June 2020.***

A full list of webinars and timings can be found at:  
[www.kangahealth.com/webinar-sign-up/](http://www.kangahealth.com/webinar-sign-up/)

Or contact Kanga Health at:  
[www.kangahealth.com/get-in-touch/](http://www.kangahealth.com/get-in-touch/)

## About the author



Kay Wesley is CEO of Kanga Health. Kay is a thought leader in global healthcare digital communications with 20 years' experience across the pharmaceutical industry, as well as non-pharma digital business leadership experience as a 'dot com' leader in the 1990s. She created and led AstraZeneca's award-winning global digital marketing team for 5 years and built McCann Health's digital agency, before founding Kanga Health.

This article features additional contributions from Kellie Sharp and Audrey Gent.

## About Kanga Health Ltd

Kanga Health is a global digital agency, providing end-to-end services to help health and pharma organisations with successful digital transformation. From strategy to development, implementation and beyond, our experts guide pharma teams and customers every step of the way to deliver projects that are always value-driven, on time and excellence derived.

### References

1. Deloitte 2018 Banking Survey





A close-up photograph of a scientist in a white lab coat and blue gloves, using a pipette to transfer liquid into a microplate. The background is blurred, showing other lab equipment.

## Improving access and reimbursement for specialty therapies

As specialty therapies move toward long-term maintenance use and as treatment times grow longer, government and commercial payers are scrutinising the economic value of new treatments more closely. In addition to efficacy and safety, clinical trials increasingly must demonstrate a meaningful impact on patients' lives. Several executives at ICON share their thoughts on how clinical development can better satisfy the evidence needs of health technology assessment (HTA) bodies and payers.



## In what ways are R&D protocols not aligned with reimbursement and access processes, and how is this impacting the industry and patients?

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**Arabella Stanley:** Historically, reimbursement was not a consideration during protocol design for clinical trials, but that must now change.

It's worth noting that in 2017, of the 50 drugs submitted to HTAs, only 20 were reimbursed because of various evidence challenges. HTAs frequently question the relevance of endpoints, study populations, comparators, study geographies, and even the design of quality-of-life (QoL) questionnaires. They use the same process to review specialty drugs as non-specialty drugs, which doesn't allow for any unique circumstances, such as, for example, when there might be data on only 20 patients in a rare disease study with no comparator. If they find any holes in the data, they tend to either restrict coverage to a subpopulation, or require more evidence – either from a retrospective real-world study or from a fresh trial. So, by not incorporating the needs of payers early into trial designs, you risk spending more money later on and delaying access to critical medicines for unmet medical needs.



# How should the industry evolve their trial designs and processes to pre-empt market access issues further down the line?

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**Kelly Franchetti:** The key is to adopt a true internal patient focus. The culture of clinical research is starting to shift from one directed by researchers to one driven by the needs of patients. Technology that constantly monitors and communicates with patients in real time makes it possible to assess the results of therapies at a granular level and over a range of real-world conditions. Involving patients and care partners in developing new therapies and trial designs and meaningfully engaging with them throughout the development and post-market process helps in generating irrefutable evidence of the value of therapies to patients in the real world.

**Tanvi Ahuja:** Early economic models (EEMs) should also be used to inform clinical development decisions, to develop evidence generation plans, and to support early pricing and market access discussions. It can answer questions such as “Is it worth the investment to collect better data?” “Where are the biggest gaps in existing evidence?” “What will be the economically justifiable price?” And even, “How will the choice of comparators, sub-groups, and efficacy inputs impact results?”





# In what ways can you bring the voice of the patient into trial design?

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**Franchetti:** The patient voice needs to be incorporated into all phases of research and commercialisation, and the earlier the better. Trials in the oncology and immune disorder space are beginning to do this.

In rare diseases it is even more important to speak to the patients and care partners as often there are not many other options in clinical research to choose from, and it's important we don't assume their wants, needs and barriers. The rare disease populations are very unique and we need to fully understand the ecosystem/nuances surrounding them.

Consider the example in which a very sick child with a rare disease who is ventilator-dependent and wheelchair-bound has to travel back and forth to the trial site. It would be easy to assume that the parents would welcome a home nurse trial visit, but historically, many parents of children with rare and orphan diseases have given feedback opposed to a home visit because they view their home as the only space where their child feels safe from being poked and prodded and made to feel uncomfortable.

We rely on a variety of means – everything from one-on-one in-depth interviews, in person workshops to video journaling a 'day in the life of a patient' to gain a robust understanding of the patient perspective and perception. And, while there's no substitute for direct patient input, it's also equally important to also gather insights from caregivers, advocacy groups, and investigators.

As for digital technology to collect patient-reported data, it's a phenomenal tool, but it also may not be right for every study or every patient. You really need to look at your patient population and consider factors such as patient age, health literacy, and socioeconomics. It is also imperative to consider what data is being collected and the rationale behind it. Patients want to understand why the monitoring is important and how it can drive their clinical outcomes and care.



For a long time, real world evidence (RWE) generation has mostly been seen as something that happens after approval, but that's starting to shift. How can RWE be implemented into studies from an early stage, and how can you ensure it is gathered in the way that will help most with eventual access?

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Bill Row: Randomised clinical trials (RCTs) are limited in that they do not address real-life utilisation and real-world performance for new drugs. With the availability of RWE to do just that, stakeholders' traditional requirements for evidence are evolving. RWE can estimate the effectiveness of a therapy in actual clinical practice, reflecting a larger population and longer-term outcomes.

Of course, lack of access to consistent real world data has historically been a problem. Accessing these data can be costly or time-consuming, which raises the question: how can we be more efficient and effective in obtaining and implementing RWE?

Devising a comprehensive RWE strategy can ensure that smart decisions are made in how to best choose, synthesise, and analyse available real world data (RWD) assets. By identifying what evidence will support regulators' and payers' decision-making, sponsors can develop an evidence generation plan across the product life cycle to leverage outputs and identify data gaps.

As clearer direction from stakeholders is released, confirmed and put into practice, there is major potential in the implementation of RWE generation strategies. While clinical trials will remain the most important source of knowledge for products in the early development stages, the impact of RWE and RWD on clinical trials and commercialisation will continue to grow.



# Taking all of this into account, what might an ideal trial look like, in terms of one that would be most likely to lead to early access for a specialty medicine?

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**Ahuja:** At ICON, we have a process for working closely with our clinical trial teams at an early stage to make sure that the protocols meet the needs of HTAs and payers. One of the keys to success is early engagement. In one amazing case, we had patients, caregivers, payers and patient advocacy organisations all review the protocol beforehand — a process which will likely pre-empt many of the challenges that could otherwise occur later on.

**Stanley:** We believe that the best results come from an integrated approach that draws on expertise in real-world evidence strategy and analytics, patient insights and engagement, patient-reported outcomes, language services, strategic regulatory services, pharmacovigilance and risk management.

## About the interviewees



Bill Row is divisional principal, real world evidence strategy and analytics at ICON



Arabella Stanley is principal, global pricing and market access at ICON



Kelly Franchetti is vice president, global head patients insights and engagement at ICON



Tanvi Ahuja is senior analyst, global pricing and market access at ICON

## About ICON

ICON plc is a global provider of outsourced development and commercialisation services to pharmaceutical, biotechnology, medical device, government and public health organisations. ICON supports programs across all stages of drug and device development, from endpoint selection and PRO development, through clinical trials, to post-approval and scientific publication. ICON delivers integrated market access, pricing, communications and health economics solutions to demonstrate product value and support brand success around the globe. For more information visit, [www.ICONplc.com/access](http://www.ICONplc.com/access)





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# eyeforpharma 2020: Redefining value for COVID-19 and beyond

The coronavirus pandemic was front and centre of everyone's minds at this year's spring eyeforpharma conferences – not least because the usual locations of Barcelona and Philadelphia had been swapped for completely virtual events. Nevertheless, with most speakers still in attendance, it was clear that the industry is keen to overcome the difficulties of lockdown to work together through these difficult times.

The pandemic didn't just mean that most speakers were broadcasting from their kitchens – it also resulted in lively discussion on how market access might change in light of COVID-19, and indeed how the various drugs and vaccines that are speeding through trials might best be brought to a global market.

That said, pharma does not just treat COVID-19 patients, and access and reimbursement will remain persistent challenges during and after the pandemic – so many speakers opted instead to discuss ongoing trends like the use of patient reported outcomes and real world evidence (RWE).

Here we highlight some of the most interesting discussions to come out of the events.





Image above: LEO's Patrice Baudry (left) speaking with eyeforpharma's Paul Simms

## Defining value for COVID drugs

It was inevitable that coronavirus' effect on market access would be mentioned at some point during the conferences, and this job mostly fell on the Valuing Innovation panel during the Philadelphia stream, hosted by Robert Dubois, who's CSO and EVP of the National Pharmaceutical Council.

Dubois said he believes the core principles of valuing innovation have not changed despite the worldwide disruption.

"The health economic principles driving how we think about the world today are the same as before, and will remain the same after the pandemic.

"Costs and benefits are time-tested concepts. During COVID-19, we'll still look at the cost of a treatment or a vaccine compared to the benefits, broadened to include how it could help loosen social restrictions.



"It's true that the budget impact of a COVID treatment or vaccine are tremendously different to, say, a rare disease drug, but I would assert that the core thinking around value hasn't changed. It's still related to the amount we are willing to pay to save a life. We may come to a deeper understanding and say we are willing to spend more than we thought we were to save a life, but that doesn't change the fundamental principles."

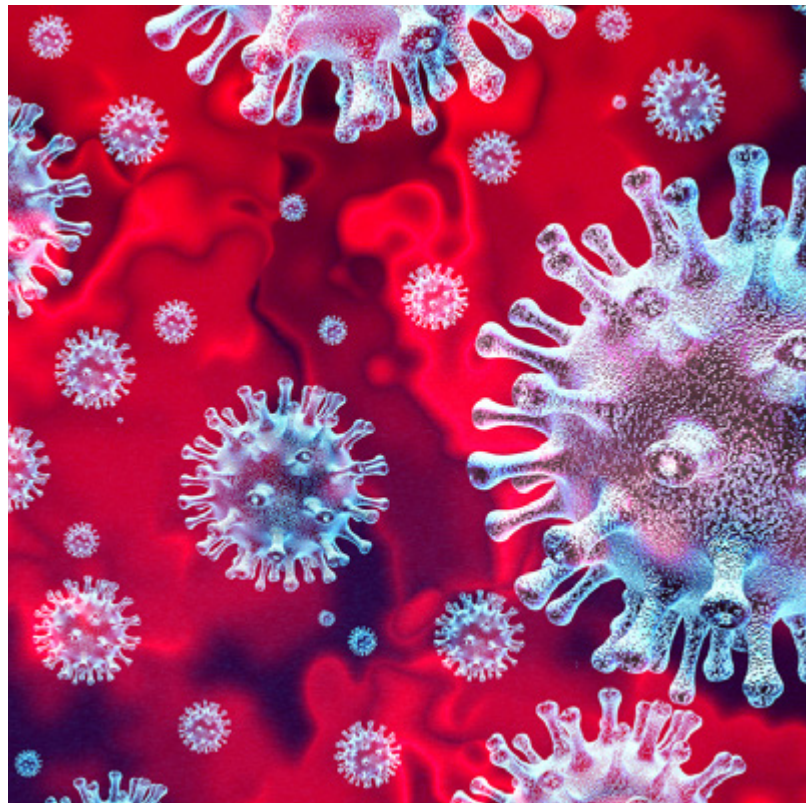


He added that the productivity benefit of a drug will likely become much more important in the wake of the pandemic.

“Diseases affect productivity. Diseases that are treated may improve productivity. That is one value of a treatment. Historically employers and payers didn’t put a lot of credence in that for value discussions. I think because of social distancing, working at home with three screaming kids and no nanny, people now understand that illnesses affect productivity in ways that they never have before.

“I would assert that productivity has always been important, but now with COVID we are going to deeply appreciate that, and moving forward I hope it becomes a part of the equation in new ways.”

Also on the panel, Sarah Emond, EVP and COO of ICER, said she agreed with Dubois’ points but was struck by how different the paradigm is when payers are trying to incentivise companies to develop coronavirus treatments compared to other drugs.



“One of the ways value assessment traditionally has been used is to signal to the innovator community what kind of incentives they need in order to invest many millions and billions of dollars to develop something. When we think about value assessment in that traditional framework we’re thinking about all of the ways that the manufacturer needs to recoup their investment from the price.

“What’s different about a pandemic is that we don’t really need an incentive to develop something new. Pharmaceutical scientists are working on this because it contributes to the social good of returning life to normal.

“In that regard, do we really need a value assessment framework to tell us what our sale price might be if we don’t need to incentivise the development?”

She said this might be an instance where the industry should think about de-linking the investment manufacturers make in R&D from the price they ultimately need to charge in order to recoup that.

“There have been several ideas passed around – everything from a prize that’s given to the person or the organisation that develops the first vaccine to a Netflix model like they’re using in Louisiana for hepatitis C, where we set a fixed price to get as much of the vaccine as we can to an individual state or country.



“One of the things that value assessment frameworks have forced us to do is have a grown-up conversation about what parts of the social surplus created by the manufacturer accrue to the manufacturer and what parts accrue to society. I think when we’re faced with a global pandemic, it’s worth having a conversation about how that balance might be different, and how social surplus actually accrues to society and not necessarily to the innovator, because we’re solving a bigger problem.”

She warned that the industry should already be thinking about the affordability of coronavirus treatments and how that might affect people across the world.

“This is especially important because value assessment frameworks are typically used in developed nations with significant healthcare budgets, but here we need to send treatments and vaccines to the entire world. Many countries do not have huge healthcare budgets. So affordability is going to be a really important part of this conversation.”

## Bringing the patient voice into value

Despite the ongoing pandemic, most speakers opted to stick to their original plans and take a wider look at where market access in pharma might end up in a few years’ time regardless of coronavirus.

In a fireside chat with eyeforpharma CEO Paul Simms during the Barcelona stream, Sunovion’s senior vice president of sales and market access Matt Portch, in keeping with his unusual job title, said there is “a lot of opportunity in taking value-based discussions to physicians and eventually to patients as well”.

“We need to make sure we talk to them about not just the safety and efficacy of our brands but also the value of the product depending on the metrics they’re looking at – whether it’s quality of care, taking costs out of the system, etc.



“You have to be a little bit more unbiased for them to be willing to have this discussion – often you have to say, ‘My product doesn’t work there, let’s identify the places it does, and where it doesn’t let’s figure out what else we can do’. For example, in mental health we might suggest cognitive behavioural therapy (CBT) as an alternative approach.”

Moderating a panel on Access and Affordability during the Philadelphia stream, Sue O’Leary, who leads the market access practice at Prime Global, noted that when her organisation speaks to payers, “they often flag what sort of outcomes they’d like to see in studies”.

“Quite often they’re disappointed when they see product profiles and study designs that don’t really take account of that,” she said.

Similarly, LEO Pharma’s EVP Patrice Baudry, noting that pharma is now trending towards providing solutions more than products, said that companies’ target product profile should “not only be the features of the molecule, but also how it helps patients, how we build different types of support”.

“That has been the case for a while, but now I’m really starting to see that accelerating.”

Asked how companies can have the correct metrics in place to ensure they are not just paying lip service to patient outcomes and values, Baudry highlighted the importance of making sure things are driven by real world data.

“When you are a company of our size you need to be smart because you don’t have the big pockets of larger pharma. It very much needs to be a culture where you track at all levels the opportunities you can have with key opinion leaders and other stakeholders. That gives us the opportunity to compensate for the deficit of size and a lower budget.”





However, EMD Serono's vice president of global patient insights and advocacy, Hazel Moran, noted during the Access and Affordability panel that pharma needs to help shape the regulatory environment to make these approaches more commonplace.

"It's great to hear from patients as an individual component but if the regulatory system doesn't align with allowing us to take into account that voice it's a challenge," she said.

"There's an opportunity for us to shape the environment in which we work."

She added: "We really need a true cross-functional collaboration because we all play our distinct roles."

She used an example of her colleagues partnering with an MS patient group to create patient reported outcomes early on in development.

"We've seen a tremendous transformation from what we were thinking of initially to where we are landing later on. It has really made a huge impact on the approach we took by making sure we don't assume anything and ask patients what matters most to them at the end of the day.

"I will probably never again hire a brand lead who doesn't have market access experience. You need to truly understand and drive a commercialisation strategy behind the value that you're bringing to each of those stakeholders."



# Real world evidence comes of age

RWE is often brought up as a key factor in helping to measure outcomes that are more reflective of patients' actual needs – and indeed the topic was one of the most common for presentations during the Barcelona stream.

The various different approaches speakers took to the subject showed that we are now entering an era where RWE has matured and become much more sophisticated.

Christian Born Djurhuus, VP and head of digital transformation, global development at Novo Nordisk, was another speaker who said he advocates for keeping product launch and the patient voice in mind from the earliest stages of development. But, as he explained in his fireside chat, despite being one of the best methods of assessing a drug's value benefit, RWE is traditionally something that can only be collected post-launch or as part of managed access agreements.

Djurhuus suggested that pharma should be starting to look at methods of gathering what he calls 'pseudo real world evidence' early on in development.



"We all aspire to demonstrate the value of our products in a real world setting. Yet, for obvious reasons that's not possible pre-approval of said drugs," he said.

"Society, and payers in general, will pay for the value that our products bring to that society. So I don't think there's any way around it – we need to figure out how to deal with this.

"I believe that we can move towards that using technology, by having more liberal eligibility criteria for trials and having more real world setups of our studies – hence 'pseudo' real world."



At the same time, he said that it's important to ensure that RWE gathered in such a way is as close as possible to the integrity of data from randomised clinical trials (RCTs) – which he believes “will always be critical in terms of new drugs and figuring out what the true value is to healthcare”.

Electronic health records (EHR), for example, have been a huge part of why use of real world evidence has accelerated, but Christian said that what is still lacking is an element of randomisation from these sources that can combine “the best of both worlds” in RWE and RCTs.

He provided some examples of how Novo Nordisk is trying to tackle this – for example they have asked some physicians if they are specifically mindful of one drug for a condition, and if the answer is ‘no’ they see if they would be willing to ask their patients to take part in randomisation.

“[We need the mentality that] you can build randomisation into healthcare and electronic health records,” he said.



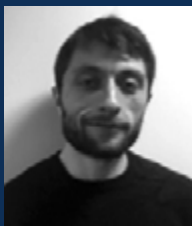
“We’re engaging with IDNs to run activities where randomisation is built on top of those records – not fully but to a large extent.

“That allows us to capture data in a similar manner to how the value-based contracting will eventually be assessed. Most of that data would be collected through electronic health records, so we need to play into that early on, and we can only do so if we’re catching it in the same environment.”

He said that collaboration was essential to such approaches.

“It’s a matter of having a joint discussion on what actually constitutes clinical value. None of the stakeholders I’ve talked to are reluctant to pay for value to society. It just has to be validated.”

## About the author



George Underwood is a senior member of the pharmaphorum editorial team, having previously worked at PharmaTimes and prior to this at Pharmafocus. He is a trained journalist, with a degree from Bournemouth University and current specialisms that include R&D, digital and M&A.





# How pharma can adapt to online engagement in a post-COVID-19 world

The COVID-19 epidemic is forcing an unexpected shift in how companies interact with stakeholders, with virtual engagement now a necessity rather than a nice-to-have – and it seems likely these changes will be here to stay.



Natalie Yeadon, managing director of Impetus Digital, says that even without COVID-19 to accelerate things, the transition to mostly virtual engagements is an “inevitability” that has been coming for the life sciences industry for some time.

Nevertheless, she says there are “lots of great lessons to be learned” from the shift in working precipitated by COVID-19, as people look for cost-effective ways to collaborate and gather insights.

“We’re going to be seeing a lot more life science companies moving in the direction of having synchronous and asynchronous online meetings,” she says.

*“In the aftermath, people will realise how effective it has been, how much money they were able to save, how good the experience was, and will likely continue with it.”*

Impetus has been working in this area since 2008 and has gained a keen sense of how the industry can best harness the potential of virtual stakeholder engagement.



## Year founded

2008

## Location

Toronto, Canada

## Areas of expertise

- Virtual and in-person advisory boards, working groups, and steering committees
- Online publication planning and development
- Execution of virtual medical education, training, and other learning activities
- Patient journey mapping
- Treatment pathway profiling
- Virtual journal clubs
- Co-creation of scientific, regulatory, educational, and promotional materials
- Strategic, logistic, and technical support
- Stakeholder management
- Content development
- Medical writing
- Events management
- Virtual event planning
- Online grant development and review programmes
- Social media engagement content development
- Virtual conference engagement programmes
- Virtual clinical trial collaboration



The company specialises in both synchronous and asynchronous meetings, and Yeadon says that both can be equally powerful for life science and healthcare firms.

Synchronous meetings involve all the participants being online and communicating at the same time, in real-time.



Asynchronous meetings usually involve giving participants a series of questions that they answer in their own time, though they are still able to interact with their colleagues via a secure platform.

This can often lead to higher completion rates than for synchronous meetings – with Impetus being able to guarantee 92% to 100% completion rates.

“Instead of having a logistically complex and expensive in-person meeting where you throw lots to the wall and hope something sticks, you can create digestible components that will allow you to have continuous interactions with the stakeholders over the course of time between a cross-functional team,” Yeadon explains.

She says this can help clients transition from the typical paradigm of the education model to what Impetus calls the ‘authentic partnership model’ – truly working with stakeholders as partners.

*“Issues don’t just evolve overnight – sometimes they pop up over the course of a year. How great would it be if you had these consultants available for insight gathering, brainstorming, and collaboration throughout the year?”*

“AI is on everybody’s minds, and we’re excited about eventual inclusion of chatbots – which can help lead people through questions.”

In cost analyses, Impetus has found that the average cost per word achieved in an asynchronous meeting comes to 55 cents per word, versus \$22 for an in-person meeting.

“One reason for that is production blocking,” says Yeadon. “When you have eight or more people in a meeting, you are better off with electronic brainstorming because you’re not going to get into ‘verbal traffic jams’. Only one person can speak at the same time in a real-time meeting.

“You can also have a series of different touchpoints over time, like clarification rounds and objection rounds. This gives people extra time to ruminate and process. There’s also a layer of anonymity that allows people to feel freer in their dispensation of ideas.”

This is also supported by Impetus’ data. In a typical eight-hour meeting with 20 advisors, the transcript is about 18 pages. In a typical one-hour asynchronous touchpoint with the same number of advisors, the transcript is 50 pages.



*“All of this means that there’s multiple benefits for doing longitudinal expert engagement plans,” says Yeadon. “They can be done very cost-effectively and efficiently using an online platform without having to fly people, pay for food, pay for meeting rooms etc, so that your reach and frequency can expand and you can have more touchpoints. You get more done and with less effort on the company’s part.”*

This can also facilitate engagement with people who may typically be less comfortable with face-to-face interaction.

“The majority of people who go into the medical space are more analytical in nature and aren’t used to giving knee-jerk reactions to questions,” says Yeadon. “When you use an online platform, you’re able to give them extra time to get into a flow of thoughts. They’re able to have the data right in front of them. You’re giving them more processing time, more rumination time and they get to see what their colleagues are thinking. Some of the more timid people now have a platform where they can express their ideas.”





# Adapting in times of upheaval

With flying restrictions and social distancing abruptly coming into force across the world during COVID-19, many companies have had to adapt quickly to holding online meetings like these.

Yeadon shares some examples of how Impetus has helped companies transition smoothly:

“We go through the original agenda they had planned and digitise it, discussing how we can transfer everything that was supposed to be done in person into a virtual space.



“Often it will be a combination of synchronous and asynchronous techniques – for example having a main meeting and then dividing people out into breakout sessions. They are still able to whiteboard, look at slides, write things down digitally, etc. We orchestrate that whole piece and lead people through it.”

Other times, it can actually be quite difficult to run a single, real-time virtual meeting for eight hours, so Impetus works with clients to break the meeting up into multiple asynchronous touchpoints.

*“Our collaboration or asynchronous tools are very ubiquitous, and how they’re used with whom and the outputs of those usages is really what determines the use cases.”*

Yeadon says that uses for Impetus’ tools can include everything from advisory boards on market access, government relations, and policy development to medical education, journal clubs and conference debriefers.

With more and more companies looking to harness virtual engagement, Impetus has also launched a self-serve option for those people who are already digitally-savvy.

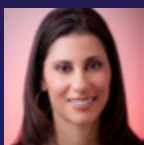


Yeadon is therefore very optimistic about the “inevitable” ubiquity of virtual engagement in a post COVID-19 world.

“We’re really excited about what the future has in store. AI is on everybody’s minds, and we’re excited about eventual inclusion of things like chatbots – which can help lead people through the questions. Our software continues to update, we’re always adding the best-in-class of every technology we can.

“The number one priority is to help everyone stay healthy. Beyond that, the virus could also cause huge economic disruption, so we would like to be able to play a small part in maintaining business and allowing people to carry on without having too many hiccups ahead.”

## About the interviewee



Natalie Yeadon brings over 18 years of experience from working in the pharmaceutical industry in a variety of roles in Canada and the US. She is currently the co-owner and managing director of Impetus Digital, where she spends her time helping life science clients connect virtually with internal and external stakeholders.

## About Impetus Digital



Based in Toronto, Canada, Impetus Digital offers a range of digital and professional services and best-in-class online stakeholder engagement tools to help life science clients collaborate and create sustained and authentic relationships with their customers, virtually.





## Breaking barriers to patient access in rare oncology

As technological advances unlock a more nuanced understanding of disease – and exciting opportunities for personalised medicine – some cancers are now being redefined as rare diseases. OPEN VIE explores the challenges in ensuring breakthrough innovation reaches everyone that needs it.

In a world of increasing complexity, the primary goal of any health system is remarkably simple: to ensure patients have access to the best care and the best treatments for their condition. However, in a healthcare environment characterised by high demand and finite resources, meeting that objective is less straightforward, particularly when it comes to accessing breakthrough medicines. With affordability now one of the biggest factors in health decision-making, today's pharma companies are under tremendous pressure to demonstrate the value of their innovations to a broad range of stakeholders, each with different definitions of value. To do so, they must capture the right evidence – but, as therapeutic understanding becomes more nuanced and stakeholder needs more diverse, it isn't easy. It's even harder in rare diseases, where patient populations and clinical programmes are naturally smaller. So how can companies build a robust evidence-base to convince regulators, physicians, payers and patients that a rare treatment merits reimbursement and adoption? It's all about preparation, collaboration and innovation.





Major advances in technology, particularly genomic sequencing, have driven a rise in orphan diseases. This is certainly the case in cancer where genomics has informed a deeper understanding of disease and progression, enabling tumour types to be broken down further into subgroups according to the genetic mutation that causes them, subsequently being classified as rare. As a result, the development of personalised medicines for less common tumour types has increased, with oncology forecast to become the leading orphan disease category (accounting for 50% of the global market) within the next five years. Tumour agnostic therapies are being assessed in basket trials of a variety of tumour types expressing the target genetic mutation to differing extents, resulting in significant variation in outcomes and making health technology appraisal a challenge. This evolution is therefore creating an inadvertent paradox: while patients' prospects are greatly enhanced by the advent of more targeted treatments, their ability to gain timely access to them is made harder by the challenges pharma companies face in demonstrating meaningful value with limited evidence.

## Exploring the challenges in rare disease through better communication strategies

**Small patient populations:** Rare diseases have small, dispersed patient populations, restricting the potential for large randomised clinical trials. In some cases, companies need to seek a licence for a product in countries where they have not been able to trial it on patients. This can present serious longer-term challenges, with reimbursement bodies often basing their decisions on data from large Phase III studies and looking for local data to support their assessment.

**Limited clinical knowledge and pathways:** In rare disease communities there's often limited clinical knowledge about new drugs, making it difficult to benchmark standards of care or existing patient pathways. Sometimes there may not be a pathway at all. Likewise, the expert community will often be tiny; in some countries, particularly those where trials have not taken place, companies can struggle to identify clinical experts to champion innovation.

**High price:** The challenges of clinical development mean it can be expensive to bring a rare cancer therapy to market. This is often reflected in high prices as companies strive for a commercial return. The subject of drug pricing has long been debated with pharma working hard to shift the emphasis from 'cost' to 'value' – but it's much harder in rare diseases.

**Limited evidence:** Traditional methods of gathering evidence are seldom available in rare cancers. Active comparators are often rare or non-existent, while both safety and long-term monitoring data can be insufficient. Similarly, selecting the right surrogate endpoint can be problematic. These factors make it hard to develop the evidence to convince payers, healthcare professionals and patients that a drug is worth using. To combat this, policies to support early access to medicines have emerged. However, these schemes – which allow medicines to be used prior to marketing authorisation subject to the mandatory capture of clinical and cost-effectiveness data in the real world – are not without risk. The example of a pharma company withdrawing a rare sarcoma treatment two and a half years after it gained accelerated approval highlights the challenges of fast-tracking access on limited evidence.

# Getting rare cancer innovations to patients safely and quickly

Planning, and then executing those plans early is key to getting innovations in rare cancers to patients safely and quickly. It's important to be proactive in considering the evidence required to gain reimbursement and access. This means engaging early with all stakeholders to understand what value means to them and the data needed to demonstrate it. Early engagement is as important internally as it is with customers and users. The different objectives of clinical trial groups and market access teams may hinder a company's ability to identify, co-ordinate and collect data that will either help pricing and reimbursement or demonstrate value to clinicians and patients. With clinical trial programmes in rare oncology naturally lean, it's important to establish – from the very beginning – the endpoints that are likely to resonate with your key stakeholder groups. This will only come through proactive (and ongoing) engagement with external influencers and joined-up thinking across the organisation. Direct engagement with patients or through patient advocacy groups (PAGs) at this early stage provides an invaluable opportunity to incorporate the patient voice.

Agility is crucial. The healthcare environment is dynamic, so companies must be able to react quickly to what they learn. Preparation is key; it's important to understand current clinical practice and policy levers that could create opportunities for your intervention. Accelerated access schemes or managed access agreements provide a mechanism to capture real-world evidence that could secure access, but without proper planning, companies can sometimes be wrong-footed when marketing authorisation is expedited and squander the opportunity to gather the best evidence.



Traditional approaches to developing evidence are unlikely to be successful (or even possible) in rare cancers. It's important to re-imagine research, evidence and pricing. Designing real-world studies is challenging, but with proactive engagement and creative thinking there's much that can be done to capture data that enhances a value proposition – ideally this should include data collected directly from patients and carers about outcomes that matter to them. For example, it's possible to develop a detailed understanding of current standards of care and use it to model what a new intervention will displace and how that will impact clinical practice. Although standard of care studies can only be implemented close to a health technology assessment (HTA) submission, the strategy can be planned well in advance.



Similarly, given the common absence of active comparators in rare cancer studies, some companies are exploring the possibility of using real-world evidence as a comparator. By marrying a clinical trial with other existing data sets, literature evidence or standard of care models, it's possible to develop innovative but relevant real-world comparators that help you demonstrate value.

## Scope for innovation

With good, proactive engagement, pharma has an opportunity to partner with payers (and indeed patients) to co-create evidence-based pricing and contracting models that support value-based healthcare. There's a growing willingness for partnership, but it's for pharma to broker discussions with ideas on what those new models might look like.

With patient populations in rare cancers extremely small, companies know that every patient in a study is gold dust; they can't afford to lose anyone to follow-up. There's increasing investment in supporting patients through clinical trials – using a variety of technologies and engagement methods – to ensure everyone recruited to a study stays on it. However, engagement doesn't end at the clinical trial; companies also need to consider long-term follow-up and how they sustain patient engagement in the real world. Innovation is critical. Successful companies seek active involvement of patients as experts by experience through building strong, long and collaborative relationships with PAGs to ensure the patient voice is present and influential at every step of the pathway.



Finally, collaboration is key. Securing access to rare cancer medicines is a team sport; companies will not win if they play the game alone. Leaders recognise the importance of building enduring partnerships with all external stakeholders to understand the landscape and the real-world value drivers – enabling them to be alert and responsive to change as it happens. The most successful organisations partner with specialists in market access, real-world evidence and patient engagement to develop patient-centred, outcomes-focused solutions that demonstrate value and drive access. The best partners have a deep understanding of the therapeutic environment, trusted relationships with stakeholders across the ecosystem and expertise in designing bespoke research programmes that capture the right evidence at the right time.

As advances in technology bring new hope in the treatment of rare cancers, health systems need innovation and support to ensure patients get access to the most effective medicines. It's a simple goal that unites us all. The only approach is to think early and work together to achieve it.



## About the authors



**Amanda Pulfer, strategic director, OPEN VIE**

Amanda has worked in the real-world evidence arena for more than 10 years offering strategic consultancy to support clients in the development and delivery of real-world evidence programmes. Prior to consulting, Amanda worked in pharma in a number of commercial roles with responsibility for launch and mature brands. More recently she has become involved in the growing area of patient engagement supporting clients to 'measure what matters' to patients in real-world studies and clinical trials and embedding the active involvement of patients and PAGs as experts by experience along the journey to successful reimbursement.

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**Cathy Wright, director of market access, OPEN VIE**

After starting her career in the pharma industry, Cathy has worked extensively in strategic market access consultancy, delivering a wide range of market access programmes and developing value strategies; ensuring their effective communication and dissemination to all stakeholders. Cathy has particular experience in hospital specialist and oncology market access and has worked across many early access projects including the Promising Innovative Medicine (PIM) and Early Access to Medicines Scheme (EAMS) submissions as well as HTA submissions to NICE and SMC.

## About OPEN VIE

OPEN VIE is a specialist market access, real-world evidence and patient-centred outcomes consultancy that helps clients understand, demonstrate and communicate value to drive change.



## Digital health and pharma – adapting to the post- coronavirus paradigm

The need for digital transformation and a response model for COVID-19 were among the topics discussed in a recent digital debate

The coronavirus pandemic has brought about a digital-first transformation as society adapts to life during COVID-19. For life science companies the evolving paradigm offers many digital health opportunities.

A recent pharmaphorum webinar examined the ways that health technology can be used to develop public utility projects and enhance healthcare communications, and how the current health emergency has made the pharmaceutical industry's ongoing need for digital transformation even more pressing.

The 10 years in 10 days: the new global digital health paradigm in life sciences webinar, held in association with Healthware Group, also proposed a response model for COVID-19 and addressed the deep transformation of marketing, customer engagement and adaptation of business processes.

Opening the webinar, Healthware's CEO Roberto Ascione noted: "Digital transformation in the COVID-19 age is a disruptor for our industry. Of course, this has been first and foremost a human crisis, but the word 'crisis' comes from the ancient Greek meaning 'change', and there are also opportunities that we can catch."



# Preparing for, and adapting to, the new normal

The coronavirus has already had a huge impact on how all companies from all sectors are operating and engaging with their stakeholders, in the process accelerating uptake of a variety of digital technologies – and the healthcare industry is no exception.

“We’ve seen digital health leapfrogging ahead before our very eyes,” said Ascione. “There’s already been a big uptake in certain kinds of technologies – they were already ramping up, but not at the pace that we are now observing.”

One consequence of this is that “customer value, especially to physicians, is profoundly changing”, particularly with respect to education for healthcare professionals (HCPs). This remains an ongoing need as medical knowledge develops and evolves.

“Healthcare professionals will still need to learn, will still need to access medical education and scientific content, but events have been drastically reduced,” he said. Since early March 2020 some of medicine’s best-known scientific congresses and annual meetings have been cancelled, postponed or, increasingly, moved to an all-digital format.

Healthcare services too face huge disruption, with reduced access to care a common issue in countries that have been put into lockdown to slow the spread of COVID-19. This access will continue to be a problem even when countries leave lockdown as healthcare services work to catch-up with delayed operations, examinations and appointments.

Ascione said: “Telemedicine, digital health, homecare, will all become regular to healthcare professionals, but there is a massive gap in understanding of these tools and how to relate to patients under this new situation.

“During this very important time frame, we believe customer value will be found in providing services that are useful in the context of COVID-19 and the aftermath of the disease’s peak.”

## The new normal for pharma

For the pharmaceutical industry the gradual emergence of a ‘new normal’ across healthcare as countries exit the emergency phase of the COVID-19 pandemic will come with some important considerations for all companies. One of these will be their need to accelerate digital transformation.

“While digital transformation in our industry has been with us for years, typically it has been a medium-term project that progresses slowly,” said Ascione. “But now, of course, under the current pressures we’ll see this accelerate.”

He suggested that, while digital transformation projects may continue to be bodies of work to be completed over the medium-term, “we believe it’s very important to have an immediate perspective as well”.





For pharmaceutical marketing, one consideration that companies are grappling with is how, and when, brand activities can start to return to normal. Looking to this next phase of the pandemic, Ascione explained that companies will need to employ 'marketing as a service' and switch from "push/interaction marketing" towards something more akin to "pull marketing".



**"With this in mind, we believe all-new sets of interactions will arise in response to new needs. Multichannel marketing will be the new normal, but we will have to adapt the messaging and offering to the new customer value reality. Technology will be the means to the end in order to offer meaningful experiences."**

One way that digital health solutions can be further enhanced to better support meaningful experiences is by leveraging 'digital empathy' constructs in the way they are designed and built as Gerry Chillè, general partner at Healthware Labs explained.

"The risk when digital tools are created for patients is that we may create impersonal interactions if we don't do this correctly. One of the things that we have been working on very hard at Healthware Labs in innovation projects that support physicians in helping patients, is really to focus on what we call empathy threads. This means digital tools that are built especially for a patient's use should have some elements of what happens naturally in a doctor-patient conversation and relationship, even if that "conversation" is happening between the patient and the digital tool itself.

"This is actually very possible with digital. As much as they can be thought of as impersonal and cold instruments, a lot can be done to create that type of relationship."

To demonstrate how these constructs can be integrated in the design, build and content of digital health solutions, Chillè showcased Paro – a robotic seal that's used for elderly patients nursing homes – particularly those suffering with dementia – and for children with autism. In appearance Paro is a cute stuffed animal, but it has built-in sensors and robotics, allowing it to move and generate sounds.

"It reacts to people interacting with it stimulating emotional connectivity via the interactions that have been programmed in it. There have been studies showing that Paro can reduce medication use, especially for stress or depression, and provide better sleep and other clinically measurable health improvements with patients," Chillè said.

Despite looking like a toy, Paro is a Class II medical device that has been through clinical trials, and the therapeutic robot offers one way to make digital health experiences more meaningful.



## Scientific events, MCM and the salesforce

To gauge where COVID-19 is having the biggest impact on the pharmaceutical business, webinar attendees were asked which areas they were most concerned about today. The straw poll found that commercial, sales and marketing engagement topped the list for more than half (56%) of those voting, followed by clinical trials (25%), patient engagement (9%), medical communications (6%) and employees themselves (3%).

Commenting on those findings and the current situation, Intouch International's managing director Ariel Salmang said: "Sales as a whole is one of the primary problems that's arising from this crisis. Access overall has become a massive issue due to the unavailability of consultancy hours, because doctors' offices are being used as triage centres and COVID treatment facilities – then there's the personal restrictions in terms of stay-home or work-from-home orders.

"How we bridge this access is becoming a central focus for us. Obviously, this will impact significantly the way commercial organisations reach out to the customers, and it will impact the way that research facilities and trials are able to recruit polling patients or even run daily operations of a clinical trial."

Consequently, the whole idea of industry engagement needs a rethink as the digitalisation of events comes to the forefront, Salmang said.



"It's probably no surprise, but what we're seeing is a significant shift towards digital channels that are able to provide detailed information or easy access to services. So, things like websites that provide tangible services or remote detailing to replace face-to-face interaction. All of this is trending up and physicians are sending a very clear message that this is where they see the value moving forward."

In tandem, companies need to continue to evolve their promotional models so that they move away from being channel-centric and become more customer-centric and insights-driven, he said.

"We need to understand that as well as doing this very quickly, we also have to do it very well. The virtualisation of engagement is not trivial, so it needs to be flawlessly executed to create smooth experiences that have no deterioration in quality vis-a-vis face-to-face visits, otherwise it's not going to receive the same level of attention," Salmang said.

This will require a greater degree of flexibility than before as physicians face increasingly unpredictable demands on their days from patients, and relevance and value will be key to cutting through the virtual clutter HCPs face.

“This will only work if you’re presenting a very concise and very tangible value proposition, and that needs to be at the forefront of everything we do. Once we have cut-through the noise, then the content we produce needs to be relevant.

“The idea that pharma companies really should be media companies has never been more true,” Salmang said. “All marketers need to be mindful of the fact that they will need a lot more content, because they are fragmenting their outreach and their engagement significantly.

“We need to be mindful that COVID-19 is changing many aspects of physicians’ lives whether those changes are directly related to COVID or just influenced by COVID.”

## Start-up responses

COVID-19 has changed HCPs’ day-to-day lives – possibly forever – and the way digital health start-ups have responded provide new ways of meeting physicians’ shifting needs.

“The digital health start-up community has really rallied to support health care institutions, frontline health care workers, and patients in innovative ways,” said Kristin Millburn, Healthware’s global head of digital health partnerships.

She cited the examples of meditation-focused company [Headspace](#) – which provided its app free of charge to all NHS and US healthcare workers – and the ‘music as medicine’ firm [HealthTunes](#), which is accelerating the launch of its app to help support healthcare workers.

Another digital health start-up responding to the emergency is Livongo. The platform for people with chronic conditions has partnered with Kaiser Permanente to offer its myStrength behavioural health solution free of charge to the US managed care consortium’s members.



The three digital health companies recognise that mental health support, always important, has taken on new significance in the midst of the global pandemic and unprecedented restrictions on movement that countries have put in place.

Another subset of digital health that’s been responding at speed to COVID-19 is that of digital therapeutics (DTx). This has been aided by regulatory changes in the US, where the FDA has relaxed its rules on DTx approvals to eliminate roadblocks for companies working to bring mental health support tools to the market.

Meanwhile, an Italian digital health start-up took yet another approach to the situation. Three weeks before the lockdown in Italy occurred, the care delivery platform [Paginemediche](#) deployed a chatbot to help triage potential COVID-19 patients and alleviate both the worry of Italian citizens and the burden on the health care system.





“This was deployed on numerous health care institutional websites and hospital portals, and allowed for the stratification of the population based on risk levels,” said Milburn.

“To date, 135,000 patients have used the chatbot. The data it generates is being shared with the WHO and has been credited with helping mitigate the risk of the collapse of services provided by the state to manage the crisis. It’s also been translated into five languages and is available for free for non-profits and other health care institutions.”

She added: “Because start-ups have the agility and speed needed to adapt quickly to a changing environment, they can make excellent partners. I think the most important thing life sciences companies need to do right now is deeply understanding how their target is feeling and what their unmet needs in this new environment are.”

## Conclusion

As customer notions of value are radically altered, pharmaceutical companies have to reframe what they offer HCPs, payers and patients, and what sorts of customer experiences they provide while doing so.

Partnerships with start-ups can be a strong way to move forward, with a vibrant digital health ecosystem available for collaborations. Allied to this, the sort of agile approaches seen in sectors such as software development can help companies prioritise their own efforts.

The current situation with COVID-19 offers multiple opportunities to keep working on pharma’s long-held goals of digital transformation, while at the same time responding to the new digital-first environment. It just needs a thoughtful deployment of digital health where execution is key.

## About the contributors



### **Roberto Ascione, CEO and founder, Healthware Group**

A digital health pioneer and recognised thought leader, Roberto originally trained first a medical doctor and then in marketing communications. A passion for medicine, computer science and human-technology interactions led to his lifelong commitment to the advancement of digital health.

Roberto is currently CEO at independent healthcare consultancy Healthware Group, which helps life sciences companies, healthcare stakeholders and start-ups navigate the digital health transformation.



**Ariel Salmang, managing director, Intouch International**

For over 20 years Ariel has formulated digital strategies and provided implementation counsel to multiple industries, from media and FMCG to telecommunications and healthcare. In the last 12 years he has focused on the digital evolution of pharma companies and the creation of impactful digital brands and sales drivers.



**Kristin Milburn, global head of digital health partnerships, Healthware Group**

In her current role at Healthware Group Kristin works to advance the growing field of digital health and digital therapeutics by forging meaningful connections between start-ups, biopharma, tech firms and beyond. Prior to this she worked at Headspace and was an original member of the Digital Medicines unit at Novartis, working to help accelerate the adoption of new digital health solutions to improve the lives of patients.



**Gerry Chillè, general partner, Healthware Labs**

As head of Healthware Labs Gerry helps companies identify and launch scalable and sustainable digital therapeutic solutions built around patient needs. Gerry's career in the health innovation field started in the US, working on early telemedicine research and pilot projects to launching the second-ever online patient community. He is a keen believer and practitioner in digital health's ability to improve people's lives and clinical outcomes.

## About Healthware Group

# healthware<sup>■</sup>

Healthware is a next-generation integrated consulting group that has been supporting marketing and sales in life sciences through its full-service agency for more than 20 years. It operates at the intersection of the transformation of commercial operations and digital health, offering a unique range of services combining design, strategy, communication and innovation with technology and corporate venturing. For information visit [healthware.group.com](https://healthware.group.com)



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