



Cancer X: Oncology shoots for the moon

Under the revamped Cancer Moonshot initiative, a constellation of researchers, policymakers, and innovators are taking cancer care to uncharted realms

July 2023: Oncology

Tackling cancer inequalities in Europe

Taking on the challenge of cancer drug resistance

War in the Blood: The battle takes shape in the burgeoning European oncology CAR-T market access space

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Deep Dive: Oncology 2023

It's been just over a year since President Joe Biden announced plans to reignite the Cancer Moonshot initiative, established in 2016 during his stint as vice president. With a target of halving the cancer death rate within the next 25 years, it seemed a Herculean undertaking.

But few areas in healthcare can unite stakeholders across industry, political leanings, and social status, quite like cancer. Evoking the collaborative spirit inspired by President John F. Kennedy's moonshot vision, over the past year the Cancer Moonshot has made remarkable progress, paralleling the unwavering dedication, cutting-edge technologies, and scientific curiosity required to boldly venture into uncharted territories, seeking breakthroughs that will transform the lives of patients.

In this issue, we take a look back at the progress made under the Cancer Moonshot programme, and shine a spotlight on CancerX, which aims to bring diverse stakeholders together to leverage digital technology to tackle the biggest challenges in cancer.

Also, find out how Daiichi Sankyo and AstraZeneca are working together to reduce barriers to cancer care in Europe, explore the challenge of cancer drug resistance with Ribonexus, review the burgeoning European oncology CAR-T market access space with Research Partnership, and hear from Phesi's Dr Gen Li as he discusses unlocking the power of data in oncology.

Plus, we hit the floor at ASCO to find out how experts view the future of artificial intelligence, and MSD examines the future oncology workforce.

For all this, as well as the latest news, trends, and events, read on.



Eloise

Eloise McLennan – editor, Deep Dive

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Cancer Moonshot:

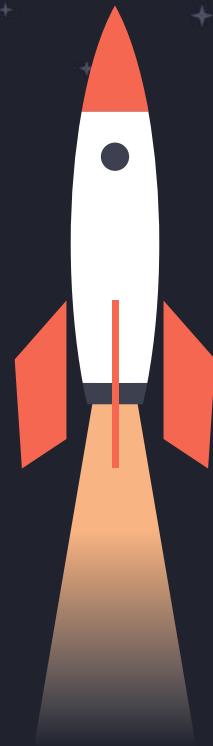
A story of hope for oncology in the US

The vision of ending cancer as we know it has long been a target for governments and politicians across the aisle. And there is a good reason why this particular disease unites competitors like few other public health initiatives. Cancer does not discriminate in who it impacts. Be it as a patient or supporting a loved one, the experience of cancer touches virtually everyone in one way or another.

As the second-leading cause of death in the US, it should come as no surprise that cancer has become a key talking point for many a political campaign debate, from President Richard Nixon's 'War on Cancer' in the 1970s to President Bill Clinton's championing of breast cancer efforts.

But in 2016, President Barack Obama sparked a new approach to accelerate cancer research and improve patient outcomes, promoting collaboration and uniting public and private organisations to pursue a noble goal.

This is the story of the Beau-Biden Cancer Moonshot.



2016

The cancer fight takes flight

Echoing President John F. Kennedy's 1961 call for the nation to "commit itself to achieving the goal, before this decade is out, of landing a man on the moon and returning him safely to the Earth", in January of 2016, then-US President Barack Obama announced an equally ambitious scientific goal during his final State of the Union address – to make a decade's worth of advances in cancer prevention, diagnosis, and treatment, in five years.

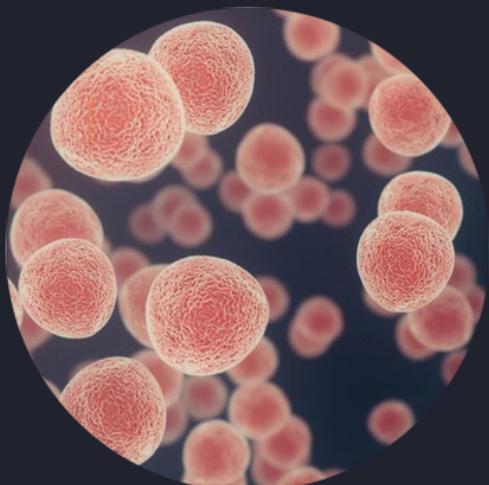




Dubbed the Beau-Biden Cancer Moonshot programme, this national effort would see stakeholders, including the National Cancer Institute (NCI), the Department of Defense (DoD), and the private sector, harnessing the country's vast scientific and technological capabilities to reduce the cancer death rate and change the experience of cancer for patients.

Leading the effort as what Obama called 'mission control', would be the then Vice-President, Joe Biden. It was no secret that Biden had a personal connection to cancer following the loss of his eldest son Beau to brain cancer at the age of 46. With Biden at the helm, the Cancer Moonshot Task Force was established to leverage federal investment, targeted incentives, private sector efforts, and patient engagement initiatives across the oncology spectrum.

One particularly influential act was the formation of a Blue Ribbon Panel (BRP), which was charged with outlining the state of the field across their topic areas, as well as identifying areas of scientific opportunity for the broader cancer community.



In September that year, the BRP presented its final recommendations to the National Cancer Advisory Board (NCAB). The ten recommendations were: establish a network for direct patient involvement, create a translational science network devoted exclusively to immunotherapy, develop ways to overcome cancer's resistance to therapy, build a national cancer data ecosystem, intensify research on the major drives of childhood cancers, minimise cancer treatment's debilitating side effects, expand the use of proven cancer prevention and early detection strategies, mine past patient data to predict future patient outcomes, develop a 3D cancer atlas, and develop new cancer technologies.

Moreover, in December, Congress passed the 21st Century Cures Act, which allocated \$1.8 billion over seven years to help transition the Cancer Moonshot from ambition to reality.

2017

Laying the foundations for innovation

The arrival of a new Commander in Chief typically heralds a new array of goals that overshadow those of the outgoing party. However, the broad reach of cancer spanned the aisle, and the Moonshot received strong support from both Democrats and Republicans. While Obama and Biden continued their efforts outside the White House, newly appointed President Donald Trump vowed to pursue a cure for cancer while in office.



In the first full year of the five-year plan, the achievements seen in 2017 showcased the potential of a united public-private front as swathes of scientists, advocates, charities, and invested parties pooled their resources. One such effort was a collaboration between the National Institutes of Health and 12 leading biopharmaceutical companies, known as the Partnership for Accelerating Cancer Therapies (PACT). The \$215 million project focused on efforts to identify, develop, and validate robust biomarkers to advance new therapies and treatments that harness the immune system to attack cancer.

Under the Moonshot, the National Cancer Institute introduced a new drug formulary. A public/private partnership between the NCI, pharma, and biotech companies, the formulary provides NCI-designated cancer centres and their investigators' rapid access to agents for cancer trial use and pre-clinical research.

Alongside this formulary, 2017 saw the establishment of the FDA Oncology Center of Excellence. Initially authorised by the 21st Century Cures Act of 2016, the centre brought together regulatory scientists and reviewers with expertise in drugs, biologics, devices, and data science to support an integrated approach to evaluating products for the diagnosis and treatment of cancer. At the core of this mission was the aim to achieve patient-centred regulatory decision-making through innovation and collaboration.

Since its inception, the centre has launched several initiatives to champion patient-focused drug development, including Project Optimus, an initiative to reform the dose optimisation and dose selection paradigm in oncology drug development, and Project Confirm, designed to promote the transparency of outcomes related to accelerated approval for oncology indications.



2018/19

Giant leaps for mankind

Continuing the trend of innovation and progress set in 2017, 2018 proved to be a transformative year for oncology in the US as the Cancer Moonshot Initiative achieved several milestones that advanced cancer research and treatment.



One such accomplishment was the establishment of the Immuno-Oncology Translational Network (IOTN), created in response to the BRP's recommendation to create a translational science network to advance immunotherapy for adult cancer patients. Comprised of multidisciplinary researchers, the IOTN aimed to improve immunotherapy outcomes and develop immune-based approaches to prevent cancers before they occur. The IOTN now consists of 32 academic institutions across the USA.

Another significant development was the launch of the Cancer Research Data Commons (CRDC), a centralised repository for cancer research data. While CRDC formed just one piece of Moonshot's broader Cancer Data Ecosystem, the platform quickly became a robust resource through which researchers could access and share data and insights across long distances, accelerating the pace of cancer research.

On the subject of community resource efforts, a core feature of several Moonshot efforts is the idea that shared resources will be used to rapidly accelerate progress for patients. One notable example is the Human Tumor Atlas Network (HTAN), launched in late 2018. Funded by the NCI, the HTAN set out to construct 3D 'atlases' of the cellular, morphological, and molecular features of human cancers. Spanning a diverse range of cancer types as they progress from precancerous lesions to advanced disease, these atlases aid researchers in identifying the molecular and cellular conditions that cause healthy cells to become cancerous and drive critical transitions in advanced cancers.



Additionally, in 2018, the Cancer Moonshot Initiative supported the launch of NCI-CONNECT, a program aimed at advancing the understanding of rare adult central nervous system (CNS) cancers. NCI-CONNECT utilised the successful infrastructure and network of the Brain Tumor Trials Collaborative (BTTC) for clinical trials. The programme fostered partnerships and networks between patients, advocates, and providers to improve approaches to care and treatment for rare CNS cancers.

Primarily, this was a ground-breaking year in terms of treatment. The FDA approved two new immunotherapy treatments for cancer: pembrolizumab (Keytruda) and nivolumab (Opdivo). These treatments are based on the body's immune system and have been shown to be effective in treating various cancers, including melanoma, lung cancer, and kidney cancer. Moreover, researchers at the University of Texas MD Anderson Cancer Center developed a revolutionary new type of immunotherapy treatment – CAR-T cell therapy.

2020/21

COVID-19 and cancer research

Understandably, the unexpected arrival of COVID-19 threw something of a wrench into the five-year targets for Moonshot. However, despite the challenges and limitations resulting from social distancing and lockdown mandates, the mission endured. Recognising the impact that the pandemic had on cancer patients and research, efforts were made to understand the intersection between the two diseases, including the impact on cancer treatments, clinical trials, and patient outcomes, and to mitigate the effects of the pandemic on cancer care across the nation.

In 2020, investigator groups from the HTAN made significant progress in advancing our understanding of how cancers develop and respond to treatment. One such team developed a profiling 'toolbox' for capturing the complex molecular characteristics of fresh and frozen tumour samples.





2022/23

To infinity and beyond

Unperturbed by the five-year milestone, President Biden announced Moonshot 2.0, a new front in the war on cancer as part of World Cancer Day, setting a new –equally ambitious – goal of reducing the cancer death rate by 50% within 25 years.



Elsewhere researchers from the PDX (patient-derived xenografts) Development and Trial Centers Research Network (PDXNet), a coordinated research programme tasked with the large-scale development and pre-clinical testing of targeted therapeutic agents in patient-derived models, demonstrated the reproducibility of PDX drug responses and sequencing results across diverse experimental protocols, which established the potential for multisite pre-clinical studies to translate into clinical trials.

In January, the nation welcomed President Biden as he began his first term at the helm of the US Government. Unfortunately, while he reaffirmed his commitment to eradicating cancer, Biden's return – five years on from the launch of the Beau-Biden Cancer Moonshot – was not accompanied by news that the programme had achieved its ambitious goal. But, if at first, you don't succeed...

As part of Moonshot 2.0, the President convened the inaugural Cancer Cabinet to establish a prioritised agenda and appointed three distinguished members of the scientific, research, and public health communities, Dr Mitchel Berger, Dr Carol Brown, and Dr Elizabeth Jaffee, to serve on the advisory President's Cancer Panel.

Just as the BRP had done years earlier, the Cancer Cabinet identified and released priority actions to guide agencies toward realising the vision of "ending cancer as we know it". These included: closing the screening gap, understanding and addressing environmental and toxic exposures, decreasing the impact of preventable cancers, bringing cutting-edge research through the pipeline to patients and communities, and supporting patients and caregivers.



One year on, in 2023, the Cancer Moonshot had announced over 25 new programmes, policies, and resources to address these five priority areas. On the first anniversary of Moonshot 2.0, the Biden-Harris Administration announced the NCI's launch of a first-of-its-kind, public-private partnership to bring clinical and patient navigation support to families facing childhood cancer. The administration also unveiled the launch of CancerX, a public-private partnership developed as a national accelerator to boost innovation in the fight against cancer and revealed that the Health Resources and Services Administration (HRSA) planned to award \$10 million to improve access to lifesaving cancer screenings and early detection including patient navigation support services, expanding on the \$5 million awarded to 11 health centres in 2022.

With approximately \$1.8 billion requested in the President's FY 2024 Budget for strategic investments in the Cancer Moonshot initiative, it is evident that the Biden-Harris Administration has high ambitions to advance the cancer effort in the US. However, with just over a year left in his first term, researchers, stakeholders, and patients will have to wait and see whether the next administration will continue the momentum of Cancer Moonshot in 2024 and beyond.

About the author

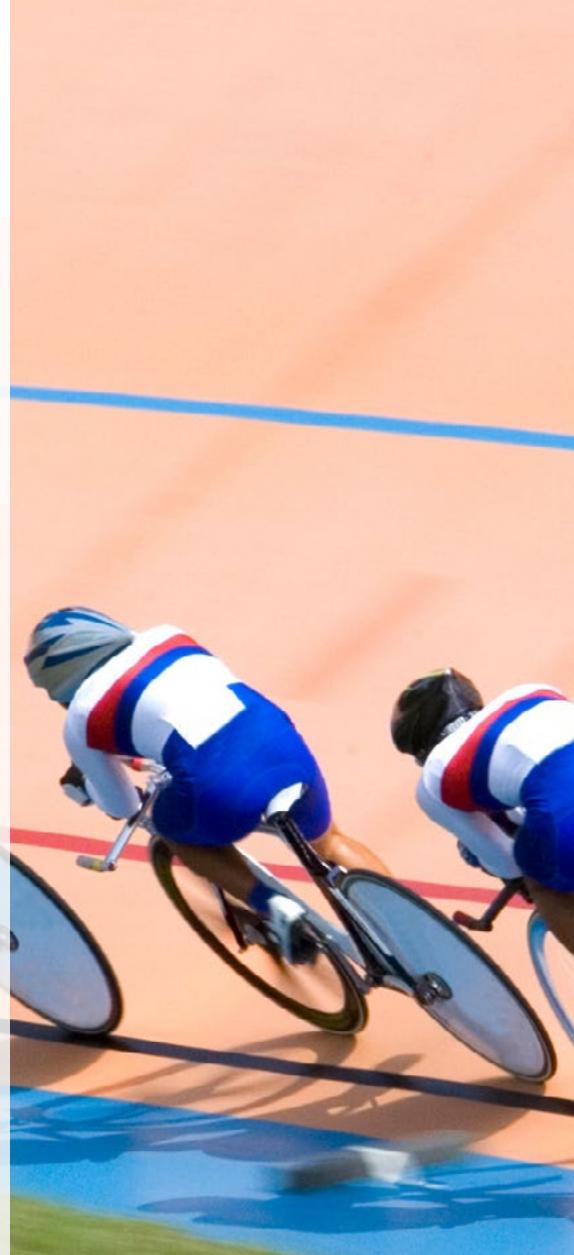


Eloise McLennan is the editor for pharmaphorum's Deep Dive magazine. She has been a journalist and editor in the healthcare field for more than five years and has worked at several leading publications in the UK.

Healthcare is a team sport: Tackling cancer inequalities in Europe

Throughout history, great scientific advancements have been made through collaboration. While the narrative of the 'lone genius' is prevalent in our society, the truth is that science is a team sport.

Without contributions from multiple people around a shared challenge, significant advances may have never been made. One thinks of the huge collaborative effort of the international Human Genome Project, spearheaded by Dr Francis Collins, MD, PhD, but only achieved by a truly vast collaboration across the world; or the crucial correspondence between Georges Lemaître and Albert Einstein, which led to what we now call "The Big Bang" model of the universe. These are two examples among a litany of advances for which collaboration was central to success.



Nowhere is this more true than for those of us who work in healthcare. Intricately connected to a multitude of factors, including societal demographics and economics, addressing the challenges of population health requires input and effort from across the healthcare ecosystem. This includes the field of oncology, where social deprivation, obesity, ageing, and healthcare expenditure, among other factors, play a major role in determining population-level cancer outcomes.

The scientific and clinical community, including the pharmaceutical industry, plays a major role in creating new opportunities for progress in healthcare. Looking specifically at oncology, we have seen astronomical advances in our understanding of the biology of cancer, leading to the advent of personalised and immune therapies – achieved through collaboration across the public and private sectors. This was clearly evident at this year's ASCO Congress, which was brimming with the fruits of collaboration in oncology research.





Pictured: Markus Kosch (left), head of oncology Europe and Canada at Daiichi Sankyo, and Greg Rossi (right), senior vice president, oncology, Europe and Canada at AstraZeneca.

Daiichi Sankyo and AstraZeneca entered into a major partnership in 2019 with the goal of combining their collective expertise to push the boundaries of what is possible in cancer care, based on a shared commitment to address high unmet patient needs. Speaking about the importance of collaboration to achieve advances in oncology, Markus Kosch, head of oncology Europe and Canada at Daiichi Sankyo, said:



“While our goal of preventing cancer as a cause of death is ambitious, we believe that the power of collaboration to create significant advances in science and technology will one day make this a reality for patients. We have already come so far – our increased understanding of the biology of cancer has led to a ‘golden age’ of biomarker-led precision medicine, unlocking innovative treatment strategies that can optimise response rates, overcome therapy resistance, and improve adverse event profiles. By combining our expertise and resources, we can accelerate and go even further.”

However, despite significant advances in care, deaths caused by cancer continue to increase and it remains the leading cause of death in people aged under 65 in the European Union. Cancer touches all of us, with every second person estimated to develop cancer throughout their lives. Greg Rossi, head of oncology for Europe and Canada at AstraZeneca, explained:



"We are an increasingly elderly population, and there are growing challenges around obesity, which we know is a key driver of the incidence of cancer. We also have the challenge of significant cancer inequalities both between and within countries, including between those who live in a rural versus urban setting. This is an urgent challenge that the European community and individual countries are looking at, but we need increased urgency and to act together if we are to make tangible progress for patients."

Main causes of death by age and sex, EU, 2020

(standardised death rate per 100 000 inhabitants)

Cause of death	Men		Women		
	Rate for male inhabitants	Rate for female inhabitants	Rate for male inhabitants	Rate for female inhabitants	
Lung cancer	20.59		Breast cancer	12.78	
Accidents	20.22		Lung cancer	10.81	
Heart attack	15.88		COVID-19	6.31	
COVID-19	15.02		Colorectal cancer	5.23	
Chronic liver disease	13.97		Cerebrovascular diseases	5.21	
Intentional self-harm	13.55		Accidents	4.68	
Below 65 years old					
COVID-19	570.53		Cerebrovascular diseases	319.47	
Cerebrovascular diseases	378.87		COVID-19	311.16	
Lung cancer	288.85		Dementia	168.51	
Heart attack	213.65		Heart attack	110.97	
Chronic lower respiratory diseases	190.29		Breast cancer	108.33	
Prostate cancer	176.97		Chronic respiratory diseases	88.97	
Above 65 years old					

(1) Malignant neoplasms of the trachea, bronchus and lung

(2) See section 'Classification of the causes of death' for details on how COVID-19 deaths were calculated.

(3) Malignant neoplasms of the colon, rectosigmoid junction, rectum, anus and anal canal

Source: Eurostat (online data code: hth_cd_asdr2)



Europe's Beating Cancer Plan provides an important framework for the region to leverage significant opportunities to improve cancer outcomes. Launched by the European Commission in 2021, it outlines current factors limiting cancer care improvement across Europe, focusing on four key areas: prevention, early detection, diagnosis and treatment, and quality of life of cancer patients and survivors. Addressing inequity is a major theme throughout – there is a significant difference in the five-year cancer survival rate across Europe, ranging from the lowest at 74%-77% in Estonia and Lithuania through to 89% in Sweden and Finland, and there are several influential factors associated with this.

"There should be no first and second-class cancer patients in the EU."

Europe's Beating Cancer Plan

Early diagnosis is fundamental to improving cancer survival

Screening and other strategies that support the earlier diagnosis of cancer are critical to avoid later diagnoses when the disease has spread and treatment with curative intent is less likely. In breast cancer, for example, screening has had a significant impact on outcomes in Europe, estimated to have prevented nearly 21,700 deaths from breast cancer per year in the period 2015-2020.

According to Europe's Beating Cancer Plan, 25 EU Member States have included population-based screening programmes in their National Cancer Control Plans; however, many programmes have not yet been fully implemented, and inequalities in access to screening persist both within and between countries. For example, coverage of the target population for breast cancer screening ranges from 6% to 90% across Europe. Rossi says there are many factors at play:



"Age, gender, mobility, and socioeconomic status are just a few of the demographics impacting the uptake of cancer screening. The COVID-19 pandemic also caused significant continuity challenges. Partnership working with multidisciplinary healthcare teams and patient advocates to ensure screening is available, equitable, and taken up by all communities must be an urgent focus."

New EU cancer screening recommendations published in December 2022 reaffirm the goal to ensure that 90% of the EU population who qualify for breast, cervical, and colorectal screenings have access to a screening programme by 2025, and recommend screenings are extended to include other forms of cancer in a stepwise approach. It is critical that this goal is met to ensure patients have an equal opportunity to detect their cancer early.

Biomarker testing is the key to unlocking targeted therapy

Significant progress has been made in the identification of biomarkers and matched therapies in oncology, with around 55% of all oncology clinical trials in 2018 involving the use of biomarkers, compared with around 15% in 2000. However, in clinical practice across Europe, there are significant variations in access to – and the quality of – biomarker testing.

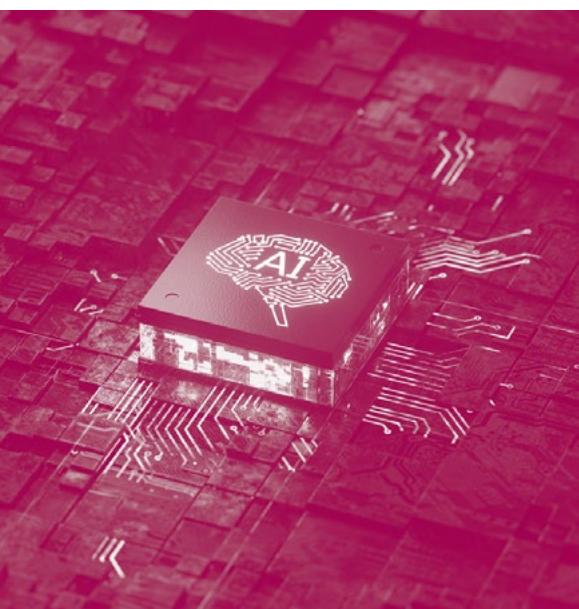


In order to address these issues, Kosch says:



"We must improve testing infrastructure, update guidelines, and educate patients and healthcare professionals about the importance of testing at diagnosis. Crucially, we must implement a parallel regulatory and reimbursement approval process for biomarkers alongside precision medicines, so that access to testing does not hold a patient back from accessing a therapy that could potentially make a meaningful difference to them."

New technology is going to play an important role in the future, says Rossi.



"We see the potential that machine learning and artificial intelligence (AI) derived systems have and believe that, among other areas, they will transform diagnostics services in the near future. For example, together with Daiichi Sankyo, we are collaborating with Ibex Medical Analytics, a leader in AI-powered cancer diagnostics. Optimised breast cancer diagnosis for pathologists using AI and improved identification of patients for targeted therapies is the ultimate aim of this collaboration."

Timely access to new innovative treatments

If and when a patient accesses a new medicine can make a significant difference to their experience and treatment outcomes. However, disparities in the time it takes for patients in different EU Member States to access new medicines following EMA regulatory approval are increasing. The duration ranges from almost immediate reimbursed access in Germany, to more than 899 days for patients in Romania. For patients with cancer, particularly those at an advanced tumour stage, every day counts.

Rossi adds:



"As pharmaceutical companies, our main part to play is the development and implementation of treatments to advance cancer care for patients. However, this is a team sport – we cannot achieve this goal by ourselves. We must support each other to ensure country reimbursement frameworks keep up with advances in science and enable patient access to new innovative therapies in a timely manner."

Together we can meet the needs of people with cancer in Europe

Improving cancer care and addressing inequalities is clearly a complex and intricate challenge that cannot be solved by a single person, health authority, or company. Recent events have shown us that a cross-sector approach, united around a shared goal and pursuing that with urgency, can overcome even the most major and complex global healthcare challenges. If we apply the same approach here, we can improve cancer care for all patients in Europe, no matter who they are or where they live.

Kosch concludes:



"While we are still far away from a world without cancer deaths, we aim to better the lives of all people living with cancer and turn the disease into a chronic or cured condition for as many patients as possible. Our alliance with AstraZeneca is an important partnership that helps us both accelerate towards this goal."

About the companies



With more than 100 years of scientific expertise Daiichi Sankyo (DS) is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology. DS is primarily focused on developing novel therapies for people with cancer, as well as other diseases with high unmet medical needs. With a presence in more than 20 countries, DS and its 16,000 employees around the world draw upon a rich legacy of innovation to realise the 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit www.daiichi-sankyo.eu.



AstraZeneca (AZ) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in oncology, rare diseases, and biopharmaceuticals. In oncology, the company's ambition is to provide cures for cancer in every form, by following the science to understand cancer and all its complexities to develop and deliver life-changing medicines to patients. AZ operates in over 100 countries and its medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com.



About the interviewees



Markus Kosch is the head of oncology Europe and Canada at Daiichi Sankyo.

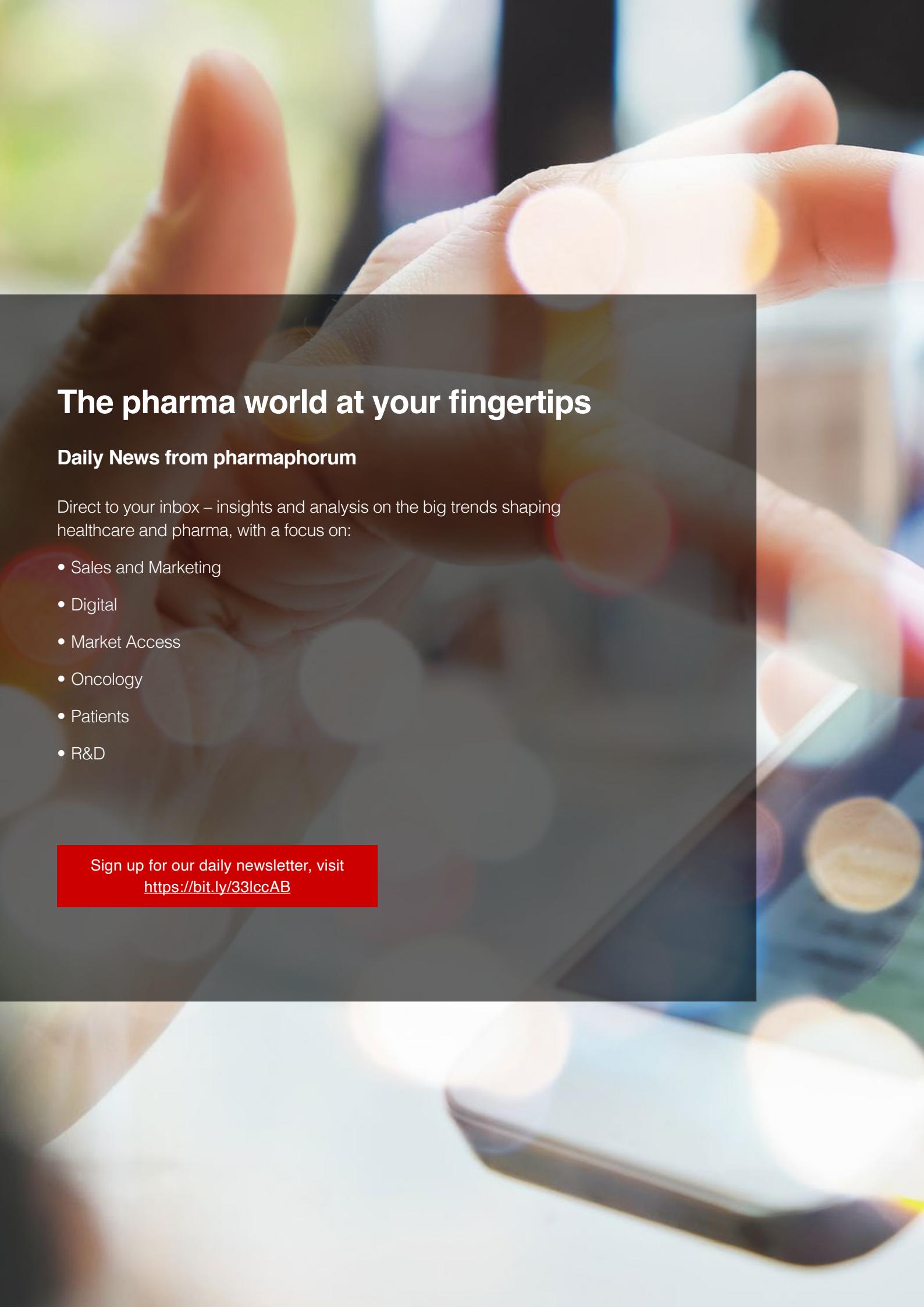
In his role, he leads the medical affairs, market access, and commercial organisation across Europe and Canada.

Kosch obtained his medical degree at the University of Münster, Germany. He has always been passionate about improving cancer care, driven by his personal experience of losing his father to colon cancer when he was 21 years old. Kosch has over 15 years of experience in the pharmaceutical industry and is a founding member of the "Vision Zero" cancer prevention initiative and think tank.



Greg Rossi is senior vice president, oncology, Europe and Canada at AstraZeneca. Through his role, he is responsible for leading the medical affairs, market access, and commercial teams for oncology across Europe and Canada.

Rossi received his doctorate in Biochemical Engineering from University College London and has since built a career in the biotechnology and pharmaceutical industry. Over the last 25 years, Rossi has worked in national (US and UK), regional and global roles for Amgen, Genentech, Roche, and finally AstraZeneca.



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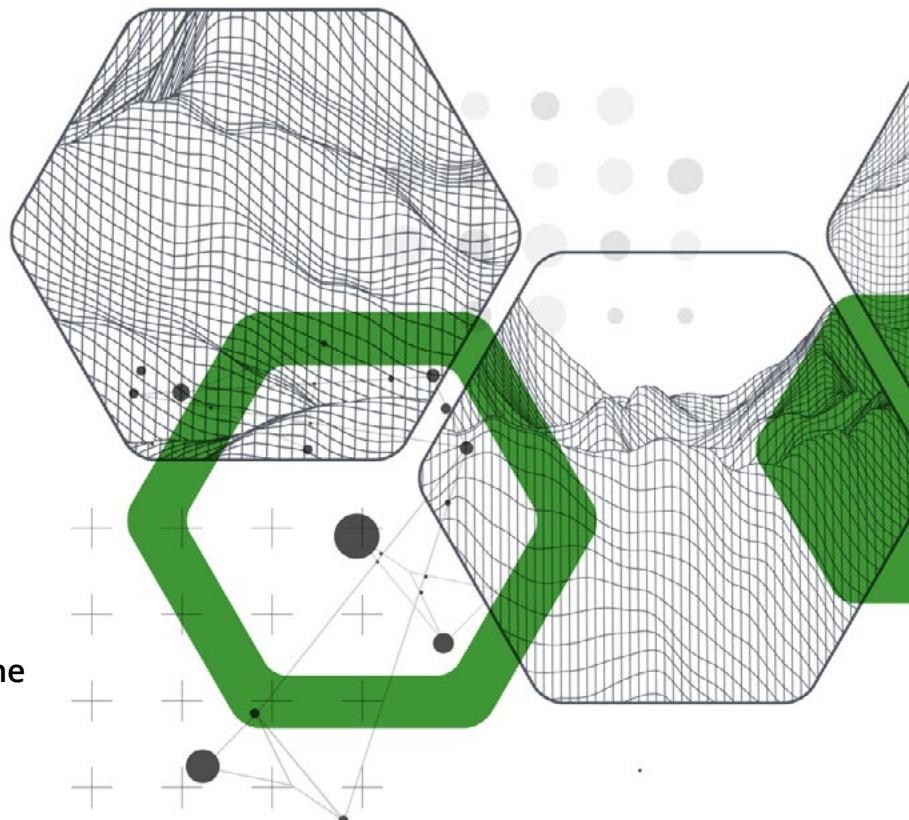
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Heard on the pipeline: Technology in oncology

It's not every day that experts from across the oncology field gather in one place to discuss the past, present, and future of cancer treatment. So, when pharmaphorum editor-in-chief Jonah Comstock hit the floor at ASCO earlier this month, it was the perfect opportunity to find out what some of the brightest minds in healthcare think of one of the biggest trends in healthcare.



How do you see digital and AI technologies shaping the oncology space in the next three to four years?



Arun Krishna

AstraZeneca head of lung cancer commercial

The digital revolution in this medical space is here to stay. There are a couple of things that are very critical for us to move at pace. One is data. Internally within AstraZeneca or externally within hospitals and health systems, how is data captured, and is there connectivity in the data space?

Once you can connect data and follow the patients longitudinally through their journey, you can make a better-informed decision through machine learning or AI or all of that. So, I believe that we need to get the fundamentals right first, which is about data. And once we have data, I think machine learning and artificial intelligence can be applied to better understand and predict which patient may be responding to a treatment, which patient may not be responding, and how we get early markers in that space.

The other thing that I think is critically important, specifically in the lung space, is that patients get diagnosed earlier. When you look at US screening rates naturally, it's less than 5%. So how can we use data, artificial intelligence, and other things to get patients screened earlier and detected earlier, so they can benefit from those treatments?

See our whole interview with Arun Krishna from ASCO 2023 [here](#).



Gregory Lubiniecki

VP clinical oncology at Merck (MSD)

With the technological advances that are taking place in the world in general, it's appropriate that they should be applied to medicine as well. And some of the ways these are being explored currently in medicine are typically in the realm of aiding either pathologic review or radiologic review of either the pathology specimen or the imaging.

They can be used to help ensure an objective read or at least provide a preliminary read, and then humans can come in and apply their expertise to make sure this preliminary read is working. In other instances, it may be being explored to help with diagnostic considerations or differential diagnoses. It's conceivable that, in five to ten years, this sort of technology may be used regularly or routinely within clinical practice in those capacities.

See our whole interview with Gregory Lubiniecki from ASCO 2023 [here](#).



Corina Dutcus

SVP advanced clinical development, oncology, Eisai US

I think this is the next step for everyone in drug development to move on because you can progress and move so much faster. As proof of that, Eisai is opening a new chapter in our storybook called deep human biology learning. Essentially, what we are doing now is emphasising having a deep understanding of the science and then translating that understanding into new ways to discover and develop drugs using AI, cutting-edge platforms, and technologies that will make more efficient what we do every day.

See our whole interview with Corina Dutcus from ASCO 2023 [here](#).

Edmond Chan

Senior director, EMEA therapeutic area lead, haemato-oncology, Janssen

I'm really excited about artificial intelligence coming into the research space. Oncology is very complex, and as we advance in genomics, we want to better understand how genetics impact outcomes and help us tailor which therapy will be best for the patient to treat and hopefully cure cancer. The data is vast. It's very complicated, and that's why AI will be extremely useful to help us to analyse and build the next level of patient-focused therapies.

See our whole interview with Edmond Chan from ASCO 2023 [here](#).



Martin Vogel

EMEA therapeutic area lead, oncology, Janssen

If you think about targeted therapies, the companion diagnostic piece is a huge issue. If you were to develop an algorithm, for instance, that could screen standard pathology slides to predict whether or not that patient is a carrier – that can help you pre-screen and identify patients much more quickly without having to do the test in every single patient – and that's already a huge advancement.

See our whole interview with Martin Vogel from ASCO 2023 [here](#).



Jaydev Thakkar

Chief operating officer, Biofourmis

From being able to detect a certain adverse event or disease, we can see AI tools capable of predicting before something happens. And as that window of prediction continues to increase – I'll give you an example: CRS.

Cytokine release syndrome is one of the critical negative effects of some of the very powerful drugs, CAR-T. These drugs are very helpful to the patient. At the same time, the risk of CRS is so high that many patients are either stuck in the hospital or just simply drop out. We already see now that we can predict with reasonable accuracy the risk of a grade three or higher CRS.

What this means is the physician can take action of saying, "Look, this patient's risk is relatively so low, I'm not going to burden this patient by making them stay in the hospital. Let them go home, and as long as they're within this two-to-three-hour range, I can bring the patient back if they do end up getting the grade 3 CRS".

Imagine this technology becomes even more predictive, and you can pinpoint which patients are likely to get it even before they're infused with the drug. And all the rest of the patients now have the freedom to be in a hotel nearby. So, I think as the predictive abilities improve, our ability to personalise treatment and personalise approaches is going to continue to grow.



Jennifer Elliott

Head of solid tumours, global medical affairs oncology, Takeda

Takeda has invested a lot in digital because customers want digital content, and they want to interact digitally. We try to partner with companies that utilise digital means to communicate scientifically. We've also done a lot with AI in predicting things like responses to certain medications, and that's all in an effort to get the right drug to the right patient at the right time, and I do see this continuing to play a role in pharmaceuticals and in medicine. The hope is you can better predict how a patient will respond to a certain drug, thus limiting unnecessary toxicity and hopefully for better outcomes.

See our whole interview with Jennifer Elliott from ASCO 2023 [here](#)

Mark Reisenauer

President, Astellas Pharma US

I would say from a technology point of view, you've got AI, you've got digital, etc., but what that is resulting in is faster development in areas we already know are very promising. And I'll give you an example. If I had to list the three hottest areas in oncology right now that are benefitting from some of this technology, they are: the progress with antibody-drug conjugates, immuno-oncology, and targeted protein degradation. I think that's great for patients. I think you're seeing those advances move very quickly, and at Astellas, those are all areas we're participating in and are making significant investments in.



Warner Biddle

SVP and global head of commercial, Kite, a Gilead Company

From an artificial intelligence perspective, within our research and development group, we're actually leveraging that now to see which patient types are going to be more receptive to this therapy and which patient groups we should look at and enrol in clinical trials, which is actually going to help us with guidelines so we can get these therapies to the most appropriate patients moving forward. And then, from a digital technology standpoint, we know there's a huge unmet need right now.

Everyone here knows and understands about cell therapy, but a lot of these patients are still working and operating in the community, and the big challenge we have, and how we're leveraging digital technology, is: how do we get to these patients? How do we get to the community physicians to educate them about cell therapy so they can get referred early enough, potentially receive these therapies, and get a cure?

See our whole interview with Warner Biddle from ASCO 2023 [here](#)





Santosh Mohan

Vice president of digital, Moffitt Cancer Center

So many ways. I don't know where to even start. It starts with prevention and screening, right? There's a lot of behaviour change that is associated with that space, whether it's tobacco cessation or whether it is managing insomnia or stress. There are a lot of multifactorial conditions associated with cancer that we treat, and digital has a huge role to play in managing those conditions, but more importantly, to drive behaviour change.

We know behaviour change is also very hard. And this is where you also have to reduce not just the incidence, but also the mortality. And so, digital plays a role in early detection. It plays a role in precision medicine. You think about digital radiology, digital pathology, digital biomarkers, and next-gen sequencing; These are all very much digital enablers for treatment. So, it plays a role in prevention and screening. It plays a role in early detection. It plays a role in accurate diagnosis, treatment, symptom management, and survivorship. You tell me where it doesn't play a role.

Smit Patel

Associate programme director, Digital Medicine Society

If you think about data interoperability, you think about infrastructure building. For example, a patient that has to go through multiple phlebotomists, radiologists, care navigators, care centres, infusion clinics, clinicians, diagnostic labs, and pharmacists.

There are so many intervening conveners and individuals that are collecting this data. What are we going to do with all this information that is out there? How can we streamline that? There's so much efficiency that AI and, essentially, digital tools can bring that can streamline care to reduce the point solutions and to reduce the gaps that still exist in the whole supply chain of healthcare.



About the author



Jonah Comstock is a veteran health tech and digital health reporter. In addition to covering the industry for nearly a decade through articles and podcasts, he is also an oft-seen face at digital health events and on digital health Twitter.



War in the Blood: The battle takes shape in the burgeoning European oncology CAR-T market access space

With the continuing evolution of the CAR-T landscape, Research Partnership speaks to payers across Europe to investigate the market access and commercialisation potential for manufacturers of these exciting, in theory, one-shot personalised therapies.

I have a vivid memory of watching *War in the Blood*, a 2019 feature-length BBC documentary about CAR-T cell therapy and the potentially revolutionary impact on the landscape of cancer treatment. The filmmakers followed two leukaemia patients in first-in-human trials in the UK. CAR-T was showcased as their only hope and a way to re-programme the immune system to kill cancers. As with any clinical trial, questions arose. In this case, key questions centred around the long-term safety and effectiveness of the personalised CAR-T, due to its potential curative intent.

As more CAR-Ts have obtained marketing authorisation in the intervening years, similar questions have also been on the minds of payers and policymakers making decisions about how – and in which patient populations – to pay for this new modality, whose upfront cost and theoretically one-time administration is difficult to assess in the same way as traditional drugs.

In this article, Research Partnership reviews the market access opportunities and challenges encountered by CAR-Ts commercialised in the EU-4 and the UK (see Tables 1 and 2). To complement our review, we reached out to 12 payers in our network with advanced therapy expertise from across the UK, France, Germany, Spain, and Italy. We discuss their feedback and the ramifications below. We also share select findings from our new syndicated tool Access CGT, a cell and gene therapy analogue access and policy tracker.



Table 1: Industry sponsored CAR-Ts with marketing registration approvals in the EU-4 and England

Brand name	Active substance	Manufacturer(s)	Indication(s)	EMA approval date
KYMRIAH®	tisagenlecleucel	Novartis	Relapsed or refractory (r/r) acute lymphoblastic leukemia (ALL); r/r diffuse large B cell lymphoma (DLBCL), and follicular lymphoma (FL)	Aug 2018
YESCARTA®	axicabtagene ciloleucel	Kite Gilead Sciences	r/r Diffuse large B-cell lymphoma (DLBCL) and high-grade B cell lymphoma (HGBL); r/r diffuse primary mediastinal large B-cell lymphoma (PMBCL) and DLBCL; r/r FL	Aug 2018
TECARTUS®	brexucabtagene autoleucel	Kite Gilead Sciences	r/r mantle cell lymphoma; r/r ALL	Dec 2020
Abecma®	idecabtagene vicleucel	Bristol Myers Squibb Celgene	r/r multiple myeloma (MM)	Aug 2021
Breyanzi®	lisocabtagene maraleucel	Bristol Myers Squibb	r/r DLBCL, PMBCL and follicular lymphoma grade 3B (FL3B)	Apr 2022
CARVYKTI®	ciltacabtagene autoleucel	Janssen	r/r MM	May 2022

Source: Access CGT as of June 2023

Learning to live with
a lack of comparators



In January 2023, Yescarta became the first CAR-T recommended for routine use for an aggressive lymphoma through the NHS in England. The NHS itself was the first European healthcare system to agree temporary reimbursement for CAR-T Kymriah a year prior to the BBC documentary. As part of a reassessment, the HTA body NICE further endorsed it after collecting real-world evidence (RWE) through the Cancer Drugs Fund and follow-up clinical trial data. This helped NICE overcome initial clinical data limitations, including a lack of comparative data that made cost-effectiveness analysis more challenging.

Table 2: Current reimbursement status and HTA pathway/rating of CAR-Ts (per indication where applicable) in EU-4 and England

	KYMRIAH®	YESCARTA®	TECARTUS®	Abecma®	Breyanzi®	CARVYKTI®
Germany (G-BA benefit)	Non-quantifiable	Non-quantifiable	Non-quantifiable	Non-quantifiable	Non-quantifiable	Under evaluation
France (ASMR rating)	III	III	III	✓	V	V
England (HTA pathway)	STA	STA	STA	Under evaluation	Under evaluation	Evaluation suspended*
Italy (HTA rating)	Innovative	Innovative	Innovative	Not yet evaluated	Not yet evaluated	Not yet evaluated
Spain				Not yet evaluated	Under evaluation	Under evaluation

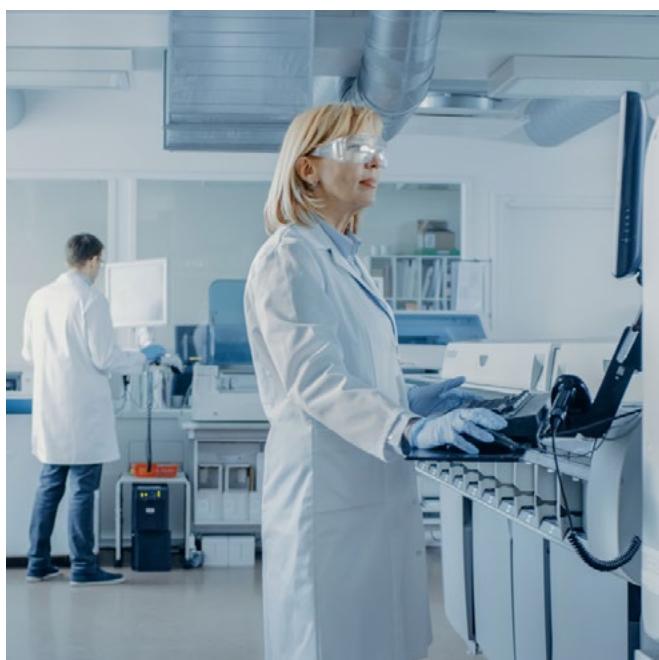
Legend: ■ Reimbursed; ■ Not Reimbursed; ✓ Approved paid early access

Source: AccessCGT as of June 2023 based on EMA, FDA, country-specific HTA reports and other official sources.

* Manufacturer withdrew submission evidence



A lack of comparative data has also prevented the CAR-Ts available in Germany from securing a quantifiable additional benefit from the HTA body G-BA. The G-BA chairman, Josef Hecken, has previously called for controlled comparative studies for these advanced therapies before seeking approval, as not every evidence gap can be bridged with indirect comparisons or RWE collection – sentiments echoed by one of the payers in our network:



“Manufacturers should have comparative trials ready with appropriate endpoints at the time of launch/HTA assessment”.

German payer



Despite these challenges, the launch of CAR-Ts in Germany has been regarded as successful by a PwC study due to their uptake; as orphan drugs, their additional benefit has been considered proven up to the annual sales threshold of now €30 million, previously €50 million.



In Italy, HTA body AIFA granted Tecartus reimbursement and an innovative medicine status in mantle cell lymphoma in March 2022, with funding from the Innovative Medicine Fund. This was despite AIFA's technical report criticising the lack of a control group, which limited the interpretation and generalisability of the results of the progression free survival/overall survival (OS) endpoints. Tecartus was also subject to a mandatory AIFA registry to resolve any uncertainty about its long-term effects.



Struggling to live with clinical and financial uncertainty



When asked about key challenges for future CAR-Ts in obtaining comparative evidence, the payers we spoke to strongly agreed on the difficulty in making pricing and reimbursement decisions based on innovative trial designs like single-arm trials (SATs). In fact, when questioned about how to ensure positive HTA evaluations for CAR-Ts, SATs were regarded as being a potential barrier, particularly among payers in France.



“Currently, it is necessary to have very solid real-world evidence, as well as clinical trial data with a comparator, in order not to obtain an ASMR V, which leads to no financial support [i.e., reimbursement].”

French payer

Notably, **France's** Ministry of Health was questioned in the French Senate in April 2023 as to whether it intends to finance CAR-Ts Abecma and Cavykti for multiple myeloma. Both therapies received a rating of ASMR V (no improvement in actual benefit) from HTA body HAS, mainly due to the absence of a comparator arm. Once the corresponding decree is published, patients will no longer have access to these CAR-Ts via the paid early access scheme.



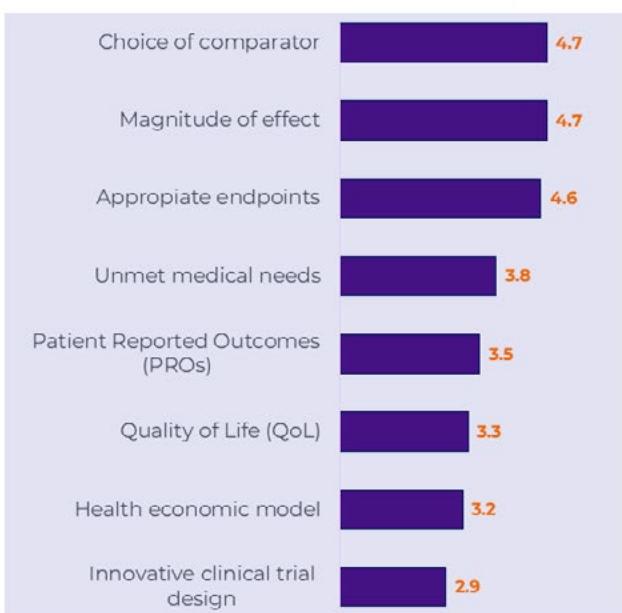
The lack of a comparator arm in a Phase II trial also led to Spain's inter-ministerial pricing commission (CIPM) questioning the long-term response of Tecartus for mantle cell lymphoma. This clinical uncertainty, along with a high budget impact, resulted in a reimbursement denial in January 2022.

“For a CAR-T to be used in a significant number of patients, there is need to present statistically significant data of OS vs the standard of care and to improve safety.”

Spanish payer

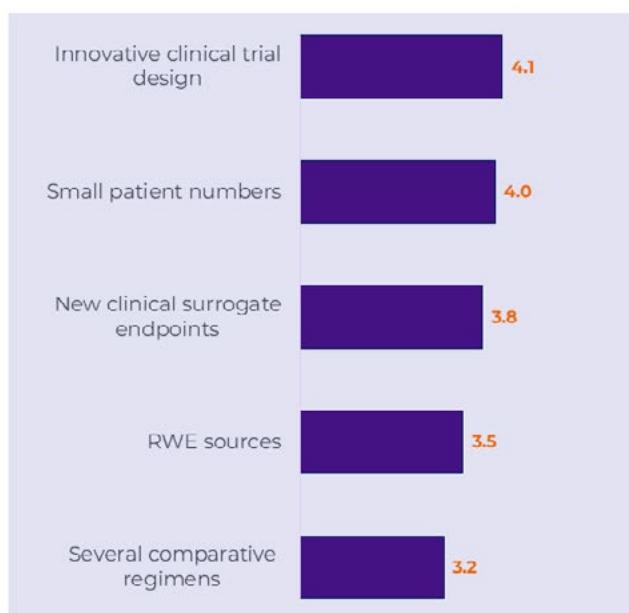


Graph 1: Value drivers for CAR-T cellular therapies for oncology
(mean value on a scale of 1 to 5, where 1 is low relevance and 5 is high relevance)



■ EU4 + England (n=12)

Graph 2: Challenges for comparative evidence generation for CAR-T cellular therapies for oncology
(mean value on a scale of 1 to 5, where 1 is low relevance and 5 is high relevance)



Could allogeneic CAR-Ts
impact the momentum
of autologous CAR-Ts?

In December 2022, the European Medicines Agency (EMA) approved Ebvallo (tabelecleucel) – the world's first nod for an off-the-shelf, allogeneic T-cell therapy (see Diagram 1). Ebvallo, marketed in Europe by Pierre Fabre, was approved for Epstein-Barr virus-associated post-transplant lymphoproliferative disorder.

With production costs of an allogeneic therapy being lower compared to autologous CAR-T, most of the surveyed payers anticipate therapies such as Ebvallo to result in an easier reimbursement evaluation and to drive the overall price of CAR-T prices down.

“I hope this will have an impact and above all that the manufacturers will lower their prices [of CAR-Ts as a whole].”

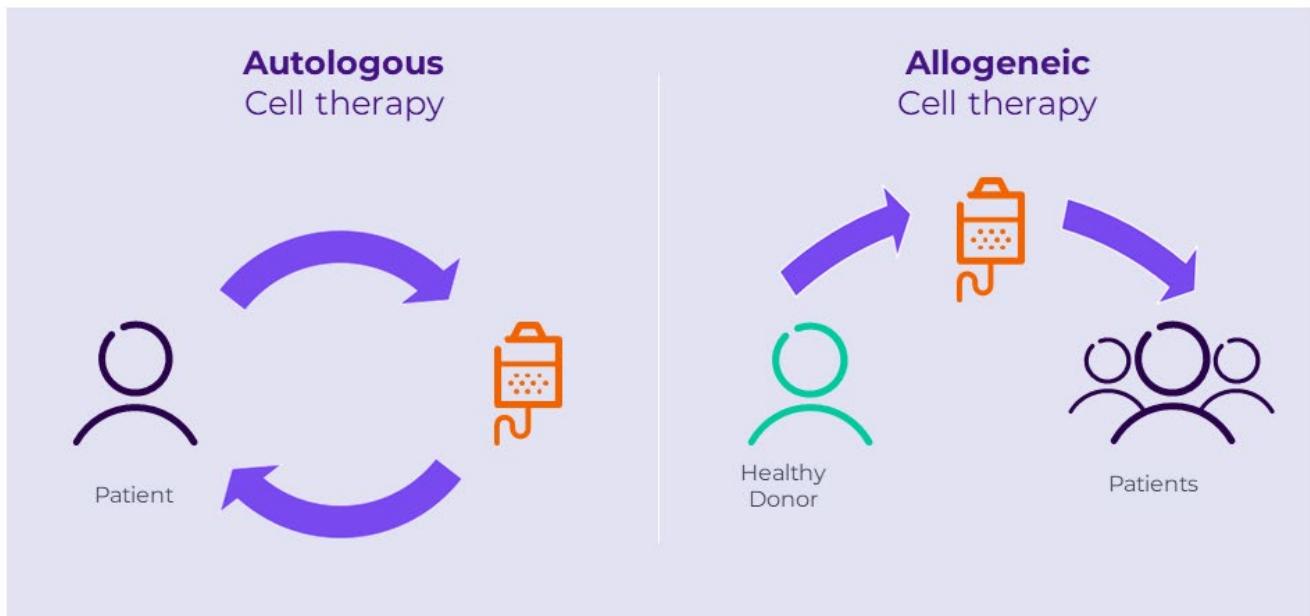
French payer

However, one German payer did comment that Ebvallo may have limited impact, considering the small populations involved:

“The estimated number of patients eligible in Germany per year is four to max. 20 per year, which makes it an ultra-rare disease with limited influence on pricing.”

German payer

Diagram 1: Cell Therapies - Autologous vs Allogeneic Process



Even more than autologous CAR-T, allogeneic cell therapies are still in their infancy, with safety, efficacy, and durability largely remaining to be proven. However, there is a clear unmet need among patients in which autologous CAR-T is not a viable option for clinical and/or logistical reasons, and for a patient subset who relapse after autologous CAR-T.

Implications and outlook

The industry needs to continue highlighting the curative potential of CAR-Ts for a sizeable target population, despite European HTA bodies having made few adaptations to their value assessment frameworks to accommodate their specificities to date. Translating the curative intent into a demonstration of long-term societal cost-offsets is key to helping manufacturers argue for payers to consider a budget impact analysis that includes costs and savings beyond the drug or healthcare budget.

As some CAR-Ts are now already reimbursed, payers could become more demanding about the level of evidence package to include robust comparative data. Given the RWE value in helping to bridge the evidence gap, industry should continue advocating for a less fragmented collection of high-quality data across the EU to support decision-making.

While we wait to understand the impact of allogeneic therapies on autologous CAR-T pricing, it will be key to align on payment deals, like longer-term outcome-based models that reflect adequate value, to overcome payer challenges with their high upfront costs, without administrative burdens. This would facilitate timely patient access to CAR-Ts at a commercially viable price, allowing them to realise their potential to truly transform cancer care, as heralded in War in the Blood.



In this rapidly evolving cell therapy space, in which it is imperative for manufacturers to closely monitor developments across countries to understand how HTA body/payer sentiment is changing through policy and actual decision-making, Research Partnership has launched Access CGT, a syndicated analogue access and policy tracker incorporating payer feedback, to support our clients with this challenge. Find out more: researchpartnership.com/accessscgt

About the author



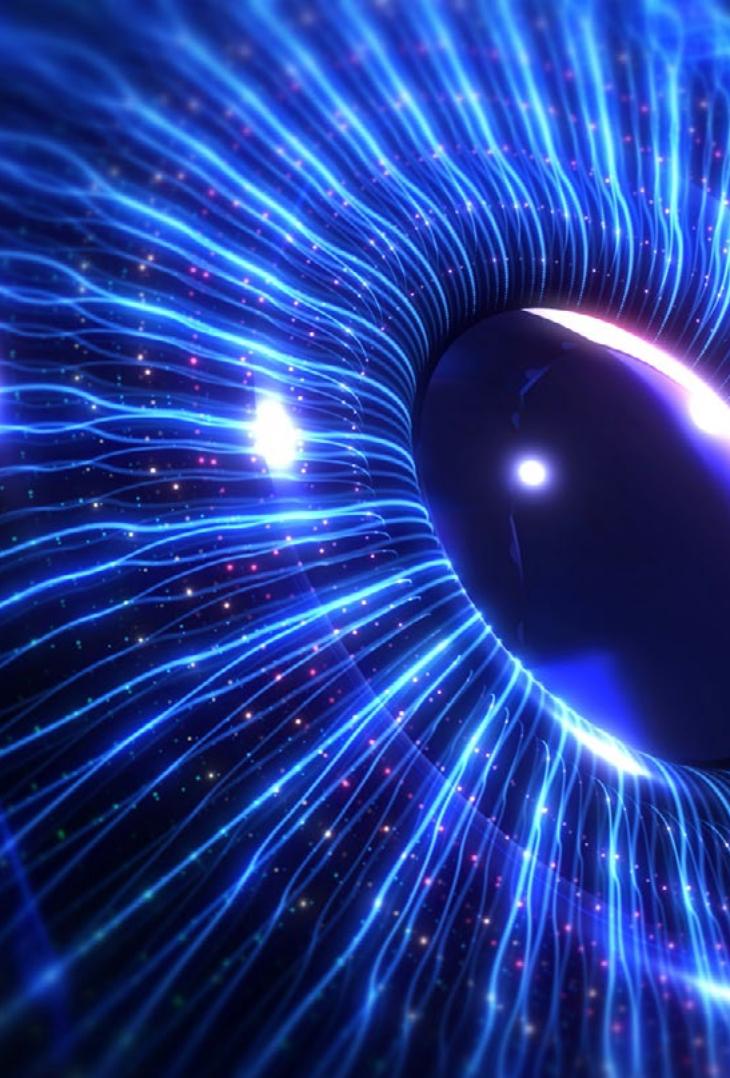
Tania Rodrigues is an associate director in Research Partnership's market access division. Tania manages qualitative global market access projects in varied therapeutic areas, with a particular interest in CGTs. Recent projects have ranged from understanding payer perceptions of the clinical value, HTA, and pricing potential of CGT product profiles, to providing guidance on key policy considerations to inform pricing and payment model decisions in the CGT space.

About Research Partnership



Research Partnership, an [Inizio Advisory](#) Company, is a world-leading custom and syndicated global insights partner for health and life sciences companies that optimises commercialisation success through evidence-based, story-told insights and recommendations. We provide custom market insights, syndicated real-world insights, and market access insights for the entire product lifecycle.

Derived through rigorous research design and socialised outputs and delivered through an agile, collaborative approach by market research experts and thought leaders, our insights empower better decisions and create long-term value for patients. 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



CancerX looks to digital to solve cancer care access challenges

CancerX, a new initiative under President Joe Biden's Cancer Moonshot, looks to bring diverse stakeholders together to leverage digital technology to tackle the biggest challenges in cancer – starting with health inequity and financial toxicity. We spoke with the ringleaders of this exciting new effort.

Last year in Boston, at the John F. Kennedy Presidential Library and Museum, President Joe Biden gave a speech about his own administration's moonshot – the re-ignited Cancer Moonshot, first initiated in 2016, but given new life by the Biden administration in 2022.

Biden, who lost a son to cancer, has said that this effort is one of the reasons he ran for presidency.



"The goal is to cut cancer death rates by at least 50% – at least 50% – in the next 25 years; to turn more cancers from death sentences into chronic diseases people can live with; to create a more supportive experience for our patients and families; and to update our fight against cancer," Biden said at that event last year.

Image credit: The White House, Public domain, via Wikimedia Commons





"It's a disease we often diagnose too late and have too few ways to prevent it in the first place; where there are stark inequities based on race, disability, ZIP Code, sexual orientation, gender identity, and other factors," he went on. "We don't do enough to help patients and families navigate the cancer care system. We don't learn enough from their experience as patients. We don't share enough data and knowledge to bring the urgency we need to finding new answers. But for each – for each of the ways we know cancer today, we know we can change the trajectory."

The rhetoric starkly sets this moonshot apart from the "War on Cancer" Richard Nixon declared in 1971. It's not merely about funding scientific research into new cures and treatments, though that's certainly a part of it. It's also about being honest with ourselves as a society about the barriers that keep people – especially marginalised people – from accessing existing cures and treatments.

Enter CancerX

In February 2023, a year after reigniting the Cancer Moonshot, the Biden-Harris Administration announced a number of new initiatives, including CancerX, a public-private partnership in the vein of successful Department of Health and Human Services (HHS) innovation programmes, such as KidneyX, which would, according to a White House Fact Sheet, "drive support for and accelerate the development of biotech and health tech startups solutions focused on the continuum of cancer care, including prevention, detection, treatment, and transitions in care."

CancerX's inaugural project has already begun, focusing on improving care equity and reducing financial toxicity.

Along with the HHS, the Office of the National Coordinator for Health IT, and the Office of the Assistant Secretary for Health (OASH), this effort is being led on the private side by the powerful team-up of the Digital Medicine Society (DiME) and the Moffitt Cancer Center.

And just last month at ASCO, CancerX announced 91 founding members from across the healthcare ecosystem that would help make the CancerX Accelerator a reality, including names like AstraZeneca, Takeda, and Genentech, as well as a who's who of healthcare providers, payers, and digital health and healthtech companies.

"We have ensured that when we welcome founding members, we are not leaving one or the other member behind," Dr Smit Patel, DiME's associate programme director, told pharmaphorum at an ASCO sit-down. "We have patient community groups; we have health systems and organisations who can do some of the implementation and demonstration work. Across the board, whoever we need at the table to drive forward progress is at the table."



"Where are their gaps?" Jennifer Goldsack, DiME's CEO, asked. "Where are their questions about what good looks like? Let's answer those questions. Let's address those issues, then let's really foster and encourage and bring to maturity those innovative companies to be in a position to implement those best practices. And then let's create an environment where we can actually implement those new best practices. And we strongly believe that this is going to do everything we need it to, to drive the promise of innovation."

Image: From left to right: Stephen Konya, Dr Catharine Young, Santosh Mohan, and Jennifer Goldsack at the CancerX launch event at ViVE Nashville, US in March. Credit: HLTH

The CancerX game plan

The Biden-Harris Administration originally described CancerX as an accelerator, but its organisers see the accelerator as one part of a multi-pronged approach to answering the question of how digital technology can help address pain points in cancer care and care access.

Specifically, DiME and Moffitt have envisioned a "flywheel" approach involving evidence generation, the accelerator, and demonstration projects, that together will move the field forward and solve problems.



While Moffitt brings a wealth of experience with cancer care, DiME brings not just a strong background in digital health, but also a record as a convener that can bring many stakeholders together and orient them around an evidence-driven, systematic approach to problem-solving.

"We have to intentionally think about a whole new approach to caring for people with cancer," Goldsack says. "Taking a data-driven approach that harnesses all of the different tools we have in the digital toolbox pairs it with expert clinicians and clinical expertise, and brings it all together. And that's why CancerX is so important, because we are taking this big tent approach, we're doing evidence generation, we're building and supporting the next generation of innovators, and we're putting it into practice to make sure it works in this complex care environment."

The first accelerator cohort is set to be announced in the latter half of 2023. In the meantime, DiME and Moffitt have been hard at work recruiting those 91 partner companies and are now working with them to do the evidence-generation work and to identify specific problems and gaps in care, as well as to build a governance model and appoint a steering committee to make the partnership self-led and self-sustaining. They'll select companies for the accelerator with an eye towards solving the particular problems they've identified, and then cascade into demonstration projects with the most promising of those companies.



The first project: Equity and toxicity

When it comes to financial toxicity and health inequity, that first step of evidence generation is an important one, Patel says, because the industry isn't always able to recognise the inequities that exist – a crucial first step in addressing them.

And while financial toxicity may exist across the board in healthcare, it's especially prevalent in cancer.



"Patients with a cancer diagnosis are 71% more likely to face an adverse financial event and 2.5 times more likely to declare bankruptcy," Santosh Mohan, VP of digital at Moffitt, told pharmaphorum. "This problem is real. It's real in those big numbers, but it's also real with people. People uproot their lives and move to a different state. And we never think about where the money for travel is coming from. Where's the money for childcare coverage coming from? What is that financial burden on people? It's not just always about insurance and hospital and care."

"When someone is not able to afford the medical treatment, it goes back to life savings. So whatever life savings they have, they use it for cancer care," Patel adds. "[Then] they have to rely on the supporting network. So, your parents, your grandparents, your kids – it's a whole family income that gets eroded just for the medical costs. I think it's critical that we identify right, best practices when it comes to, not just access to care, but [...] access to affordable care."

And cost of care is not the only problem. For instance, unequal access to clinical trials leads not only to poorer-quality trial data, but also to care inequity, as trials often represent the best treatment options in cancer care.

"How can we overcome the maldistribution of the greatest sort of cancer expertise and the patients who need care?" Goldsack asks. "Traditionally, how can you access a clinical trial? You need to be near a centre of excellence or an academic medical centre. We know there's an opportunity for many more people to go onto a protocol, but that's not available to them today in their local cancer facility. How can we use things like clinical decision support, for example, and other sorts of AI-based tools to try and support getting as many people onto protocol as possible? How can we think about optimising the chances that every single person with a cancer diagnosis gets onto the therapy that is most likely to save their life?"

And even in routine care, care shortages and delays can take an enormous toll on patients.



"Hearing that you have cancer is devastating by itself. The worst is when they hear that you have to wait one month to even see a doctor for the first time," Patel says. "And I think that is important. How can we bridge and curb that gap? How can we triage and have good care navigation systems in place that will help individuals who are diagnosed with cancer not to have to wait one or two months to access care, no matter their status?"

These are just some of the sorts of problems that the first effort will address.

Image: Santosh Mohan, and Jennifer Goldsack at ViVE 2023.
Credit: HLTH



Part of a larger solution

Goldsack, Mohan, and Patel don't believe that digital solutions can solve all of these problems. In particular, cost of care is an ongoing conversation that will likely need a systemic solution. But in the meantime, digital solutions can improve care navigation, access to trials, and potentially create a framework to address the worst of these cost issues.

pharmaphorum asked Mohan about the awkwardness of working with the full spectrum of stakeholders to reduce cost of care, even though some of those stakeholders are responsible for costs being as high as they are.



"Part of this is having those uncomfortable conversations, but part of this is also thinking about where digital can make a difference?" he said. "How do we help cut down some of those out-of-pocket costs? Avoiding people having to spend to travel, people having to uproot their families to go to a different state to access NCI-designated level care without having to actually do that, and being able to access that regardless of their ZIP code or income level. So, I think there are ways where we can achieve some common ground and there are ways where we'll have to have some uncomfortable conversations as well."

Patel says that just because this initiative is focused on the enormous potential of digital to help doesn't mean that "for every nail we see [...] a digital hammer is the answer."

"There will be times where digital will help for a solution, and there will be times where it's clear demarcation where digital is not the answer," he said. "So, I think that having the recognition and identification that those two exist on the same plane, and we'll be addressing that all together, would be important."

But of course, CancerX is just one of many parts of the Cancer Moonshot, which also includes efforts around cancer prevention, increased screening, patient services, clinical trial data sharing initiatives, a coalition focused on addressing rural obstacles to care, and much more. And this current effort is just the first project for CancerX.

"This is really, in many ways, a call to action," Mohan said. "We need everyone to participate. We need the doctors, the developers, the designers, certainly the entrepreneurs, and the scientific community. We need the industry innovators, the investors again, to provide exposure and access to capital coming together with the government support and encouragement, which, thankfully, we have through this Cancer Moonshot platform, so that we can tap into more creativity to push the boundaries and to turn a lot of these aspirations into action."

About the author



Jonah Comstock is a veteran health tech and digital health reporter. In addition to covering the industry for nearly a decade through articles and podcasts, he is also an oft-seen face at digital health events and on digital health Twitter.



Phesi's Dr Gen Li on unlocking the power of data in oncology

Dr Gen Li, founder and president of Phesi, a provider of AI-powered clinical development analytics, products, and solutions, discusses ASCO, digital patient profiles, and how digital twins and trial arms can help optimise trial design.

How can sponsors ensure that clinical development in oncology delivers on its promise to become more data led?

Sponsors should increase their focus on integrating external data sets from the industry to add to the existing body of internal knowledge to better inform trial design. This includes data from historical trials, ongoing clinical trials, electronic patient records, and epidemiological studies, alongside newer sources such as wearable and telemedicine devices, as well as health applications. But more data does not automatically equal more knowledge. Analytics are essential to extract the information needed to actually design oncology trials around the insights held within.

Moving away from long-held trial planning and execution practices to adopt a data-led approach will require buy-in at a senior level to really maximise the benefits. New skills and tools will be needed, and key 'actors' in the development space – from regulators to investigators and CROs, and patients – will need to collaborate more closely. In oncology, data-led trials will ultimately accelerate the clinical development pathway, reduce patient burden, and minimise amendments – or even eliminate them entirely.



Patient centricity has been repeatedly talked about as a priority in clinical development. What measures can be taken to improve patient centricity in cancer trials?

Data holds much promise in alleviating the burden on patients across all clinical trials. Whether by reducing the need for comparator arms, shortening cycle times, or reducing amendments – data can be used to make the trial experience and execution better. In cancer trials specifically, insights from digital patient data help sponsors make sure the right patients are being recruited for a trial and assigned the most appropriate potential therapy. Digital data at patient and cohort levels can be used to identify the attributes of the patients a therapy is supposed to treat before the trial even starts, to improve recruitment and enrolment success.



By leveraging historical and ongoing oncology trial data at scale, trials can be simulated and modelled accurately. This allows safety and efficacy outcomes to be predicted for many different treatments before they are administered to patients. Reducing the need for patients to take inferior comparator or placebo medicines and managing risk in this way is key, especially in oncology, for which therapies are becoming increasingly targeted.

With data we have obtained from patients in the past, it is also possible to help us to interpret results from single-arm trials more accurately. Among other benefits, this will help us to avoid predictably futile clinical trials.

Phesi recently released a catalogue of digital patient profiles. What is a digital patient profile, and how can sponsors use them?

The first edition of our Digital Patient Profile (DPP) catalogue was published to deliver granular patient-level data for 28 key diseases – 11 of which fall within oncology. The profiles are based on more than 485,000 curated clinical trials and amendments and contain data from over 60 million patients. We have the data to create bespoke DPPs for more than 4,000 disease indications, providing detailed information on the patient population, including attributes such as age, sex, ethnicity, and comorbidities, among many other key variables.

DPPs provide a statistical view of patient attributes and can be used by sponsors to improve programme and trial protocol design by providing a clear view of the target patient population at the trial planning stage. DPPs also support wider adoption of single-arm trials by helping sponsors demonstrate efficacy and safety in relevant patient cohorts. Further down the line, the profiles can be used to develop digital twins and digital trial arms as part of clinical development strategies.



You have spoken previously about the “digital trial arm” and the use of “digital twins” in clinical development. What are the latest developments in these areas?

In clinical development, data enables researchers to simulate and predict different outcomes in a clinical trial with greater certainty. Data is collated from similar or identical trials using the same agent, with real-world patient data, to accurately model placebo/comparator outcomes and construct digital twins and digital trial arms.

A digital twin can be used to detect early signals of trial outcomes, protect patient safety, facilitate regulatory dialogue, and enhance submissions. When a digital twin is planned and implemented in alignment with regulatory authorities, it becomes a digital trial arm, or external control arm, as the FDA calls them, reducing or eliminating the need for a placebo or a comparator arm. Thanks to oncology being such a well-researched field, there is a wealth of available data that can be employed to produce digital twins and digital trial arms for many indications.

With small-group or single-arm cancer trials becoming more common in the industry, what are some of the pitfalls sponsors should look out for?

Greater understanding of the genetic drivers of cancer is leading to more targeted therapies designed for smaller patient sub-populations, with oncology research increasingly focusing on cancers with specific genetic markers. This precision inevitably also leads to fewer and smaller suitable patient populations. With a growing number of single-arm studies and small-group trials, it is critical to have a watertight recruiting process and trial design.



Single-arm trials bring an inherent degree of uncertainty that can cause problems in trial design, patient recruitment, and data interpretation – all of which can delay patient access. Small single-arm trials are not always representative of the real-world patient population, which brings complications around interpretation of the results, delays approval, and causes difficulty in obtaining reimbursement. Clinical trial designs that are not informed by data, therefore, run the risk of developing drugs that are not efficacious for the target patient population.



You have observed that around a fifth of all trials fail. How can sponsors mitigate the risk of failure?

All too often, trials are being initiated without a solid data foundation – with many sponsors still relying on a ‘gut feel’. By using data to profile the targeted patient population and implementing predictive analytics to determine projected outcomes, protocol and trial design can be optimised and feasibility studies can be carried out.



This reduces the number of patient participants needed for the trial and minimises costly delays around recruitment – and it ensures data requirements for regulatory submissions can be met. By predicting the pathway of a clinical trial before embarking on it, chances of success are high, unnecessary delays can be avoided, costs can be reduced, and failures mitigated.

In a data-led approach, it has repeatedly proven that we can prevent a failing trial from starting.



What kind of industry insights are you hoping to see at ASCO this year? What outcomes are you hoping to achieve from the event?

ASCO is always an excellent opportunity to connect with colleagues working in the oncology space, hear about breakthrough advances in medical and scientific research, and explore the key challenges facing the industry. By getting the very latest information on innovations in biology and chemistry – and advising on the best practices for trial design and execution for these potential therapies – we can support what we hope will be tremendous advances in oncology treatments and patient outcomes.



How does Phesi see data analytics shaping the future of clinical development?

The future is here and now. As digital tools and practices become a mainstay in the life sciences space, the next one to three years hold the promise of significant breakthroughs. Digital analysis, empowered by artificial intelligence, is going to transform the planning and execution of projects – and in clinical development, this will see a move away from dated, gut-feel trial protocols towards data-driven, patient-centric clinical trials.

Smarter trials, faster cures.



About the interviewee



Dr Gen Li founded Phesi in 2007 with the aim of revolutionising the clinical trials industry.

Prior to founding Phesi in 2007, Dr Li was head of productivity for Pfizer Worldwide Clinical Development, a position he assumed following Pfizer's acquisition of Pharmacia, where he delivered the first implementation of productivity measurement for clinical development.

While at Pharmacia and Pfizer, Dr Li significantly contributed to the Centre for Medicines Research (CMR) International database for pharmaceutical R&D performance, assuring the collection of key clinical trial parameters as representative of the critical path for delivery. He was also instrumental in creating the KMR productivity mode.

Previously, he earned his PhD in Biochemistry from Beijing University, and an MBA from the Johnson Graduate School of Management at Cornell University.

About Phesi



Phesi is a data-driven provider of AI-powered clinical development analytics, products, and solutions to the biopharmaceutical industry. The company's integrated offerings cover the entire clinical development process – from development planning and indication assessment to protocol evaluation, country and site selection, and trial implementation management.

Phesi has the world's largest real-time clinical development database; delivering patient-centric data science that enables biopharmaceutical companies to predict and optimise clinical development outcomes in any indication. Its database consists of 485,000 completed clinical trials, 604,000 completed research projects, >4.2 million physicians and >600,000 investigator sites worldwide.

Phesi delivers data, insights, and answers, enabling smarter trials and faster cures.
For more information, please visit Phesi.com.



Taking on the challenge of cancer drug resistance

Tumour survival, growth, and proliferation demand complex and broad biological capabilities, including proliferative signalling, evasion of growth suppressors, promotion of local blood vessel formation, resistance to cell death, replicative immortality, invasion and metastasis, reprogramming of energy metabolism, and evasion of immune destruction. Tumours are morphologically and phenotypically heterogeneous and genetically unstable, exhibiting acquired mutation, gene translocation, and differences in copy number.

Inherent plasticity and adaptability allow tumours to muster multiple mechanisms, which can act independently or in concert to thwart the actions of cytotoxic, anti-metabolic, or molecularly targeted chemotherapy. Primary or innate resistance may involve: mutation; genetic heterogeneity, giving rise to subpopulations of intrinsically resistant cells, such as cancer stem cells; or through drug inactivation or detoxification by enzyme action. Acquired or secondary resistance results from an alteration in drug targets through mutation, changes in target expression, activation of non-target oncogenes, metabolic change, increased transport of the drug out of the cell, and alteration of signalling pathways through epigenetic change.



Promising strategies to overcome resistance

Combination therapy can reduce the probability of resistance by simultaneously targeting different tumour vulnerabilities. Early detection and judicious treatment choice have dramatically improved survival rates for some cancers, but resistance is estimated to contribute to 90% of treatment failures in those with advanced disease. The impact of adaptive or intermittent chemotherapy on the emergence of acquired resistance remains to be established.

Over 20 years ago, the approval of imatinib, the first cancer drug designed to target an aberrant critical signalling pathway identified in chronic myeloid leukaemia, heralded the arrival of orally dosed small molecule agents specific for targets present only in tumour cells and with low toxicity for normal cells. Subsequent generations of tyrosine kinase inhibitors have made previously untreatable cancers, such as metastatic melanoma and Non-Small Cell Lung Cancer (NSCLC), treatable, but high initial response rates are generally short-lived, due to the emergence of point mutations, which alter target protein composition or expression.

Targeting efflux and epigenetic alterations

Efflux, the pumping out of cancer drugs, confers multidrug resistance. Inhibition of the proteins – which mediate efflux, the ABC (ATP-Binding Cassette) transporters, especially the multidrug resistance protein MDR1, also known as P-glycoprotein or P-gp – has been widely explored as a means of restoring cancer drug efficacy. First-generation inhibitors, such as verapamil, quinidine, amiodarone, and cyclosporin A, all failed due to low potency or toxicity when added to existing chemotherapy regimens. Later agents demonstrated off-target effects, such as inhibition of cytochrome P450 or inhibition of ABC transporters essential to normal cell function.

Interest in efflux modulation has returned with a fuller understanding of the genetics and function of the ABC transporter family and the identification of two further ABC transporters associated with multidrug resistance. SCO-101 (Scandion Oncology), a small molecule inhibitor of the transporter protein ABCG2, is under early clinical evaluation as an add-on to chemotherapy in patients with advanced colorectal and pancreatic cancer.

Epigenetic alteration, the switching off or on of gene expression through DNA methylation or acetylation or by modification of the histone proteins, which pack chromosomes into a compact form, is a key mechanism in multidrug resistance. Hypermethylation in the promoter regions of tumour suppressor genes correlates with resistance to cytotoxic, radiation, and biologic therapy in solid tumours.



Acquired resistance in ovarian cancer is associated with increased levels of methylation close to the hMLH1 gene, which encodes a protein necessary for DNA mismatch repair. Decitabine, a generic DNA methylation inhibitor indicated in myelodysplastic syndrome, can restore platinum sensitivity in ovarian cancer xenografts. Another DNA methylation inhibitor, guadecitabine (SGI-110: Astex/Otsuka), also holds promise in the restoration of platinum drug sensitivity.

Non-coding microRNAs also contribute to epigenetic alteration, through inhibition of DNA transmethylases and histone deacetylases, and a variety of miRNAs are associated with the regulation of resistance in several different solid tumour types. There is much interest in the therapeutic potential of miRNA targeting, although practicalities that need to be addressed include effective delivery to the site of action, the limited stability of miRNAs, and the potential for off-target effects.

Many of the major signalling pathways that are deregulated in cancers – RAS-MAPK, PI3K-AKT-mTOR, MYC, and WNT- β -catenin – lead to activation and over-expression of the initiation factor 4F (eIF4F) complex. Importantly, inhibition of eIF4F selectively affects the translation of a small number of mRNAs that mainly code for proteins involved in oncogenic events, such as cyclin-D1 and c-MYC, which drive tumour growth and facilitate acquired resistance. Housekeeping genes are not affected, suggesting that eIF4F inhibitors may be cytotoxic to cancer cells and not to normal cells.



Emerging approaches

Ribonexus is developing orally available synthetic small molecule drugs modelled on flavaglines, naturally occurring and highly potent eIF4A inhibitors. These compounds are expected to be used in combination with standard-of-care treatments; in vitro studies have established that candidate inhibitors prevent the proliferation of tyrosine kinase inhibitor-resistant solid tumour cell lines and the translation of key drivers of tumour growth.



Promising clinical data has recently been reported for the eIF4A inhibitor zotatifin (eFFector Therapeutics) when administered in combination with chemotherapy in heavily pre-treated breast cancer patients. Circulating DNA analysis found mutations associated with resistance to endocrine therapy to be decreased or eliminated following zotatifin treatment.

Another strategy with broad potential in overcoming resistance is through targeted protein degradation by PROteolysis TArgeting Chimeras (PROTACs) – bifunctional small molecules able to selectively induce degradation via the ubiquitin-proteasome system. PROTACs act by hijacking their protein target and binding it to a joined E3 ligand. This, in turn, recruits an E3 ubiquitin ligase from the cytosol to the PROTAC complex, bringing the protein and E3 ligase artificially close, resulting in polyubiquitination of the protein and its subsequent destruction by the proteasome. PROTACs are now in clinical evaluation in a number of cancer indications.

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Exploitation of other promising avenues of attack, such as modifying the tumour microenvironment and targeting DNA repair pathways, is still largely at the translational stage. Progress in understanding and combatting resistance can be expected to accelerate with the growing application of high throughput cancer genomics, cancer proteomics, and metabolomics, allowing genetic and other changes that occur in response to drug treatment to be followed during chemotherapy.

Whole genome sequencing of circulating (cell-free) DNA allows early identification of mutations associated with acquired resistance. CRISPR gene-editing has been applied in the screening of resistance-related genes, to remove resistance through genetic manipulation, and to generate modified models of resistant cells and animals.

About the author



Steven Powell, president of Ribonexus

Steven has over 20 years' international experience as CEO in public and private companies, raising over \$225M (€214.3M) in equity. In his most recent position as CEO of Belgian biotechnology company eTheRNA Immunotherapies, he helped raise €39M (\$41M) in a Series B financing round in 2022. He has extensive board and advisory experience, holding positions in the UK, US, Canada, and several European countries. Steven holds a PhD in microbiology from the University of Aberdeen (Scotland).

About the author



Ribonexus is an early-stage biotechnology company developing promising new oncology therapies. The company aims to deliver best and first-in-class drugs that restore sensitivity to current targeted therapies in those cancer patients who have become resistant to these treatments. Ribonexus has established a library of small inhibitor molecules, targeting RNA translation. The company's core intellectual property (IP) was licensed from Pierre Fabre, alongside science foundations from leading French research institutes Gustave Roussy, Institut Curie, and the University of Strasbourg.

Ribonexus was co-founded in 2021 by Adbio partners. In 2021, the company raised €4M in seed funding from AdBio partners, Credit Mutuel Innovation, and Pierre Fabre Invest.

www.ribonexus-project.com



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An oncology workforce fit for the future



To continue delivering high-quality and patient-centred care, the future oncology workforce of the NHS needs to be agile, expansive, and diverse. MSD spoke to experts to share their thoughts on what this might look like...

Remarkable progress is being made in novel areas of cancer research, which are contributing to the diagnosis and treatment of the disease. With recent reforms in UK clinical trial regulations, patients have the potential to access new cancer-targeting drugs quicker than ever before. In order for UK patients to have the best opportunity to participate in the latest commercial clinical trials, we need to see urgent implementation of the Lord O'Shaughnessy review recommendations, to address the major delays when approving new studies and recruiting patients.

Despite advancements in oncology research and development, the burden of cancer on healthcare systems continues to rise. By 2040, more than half a million people across the UK will be diagnosed with cancer each year. Record numbers of people in the UK are coming forward to have cancer checks and screenings (10,000 per day) and subsequently receiving diagnoses (around 6%). This is important progress, as it enables people to be treated at earlier stages of disease (stage 1 or 2) when survival prospects are typically higher. Although this is a step in the right direction, the challenge is to consistently deliver on screening programmes and provide timely treatment to continue improving cancer outcomes.



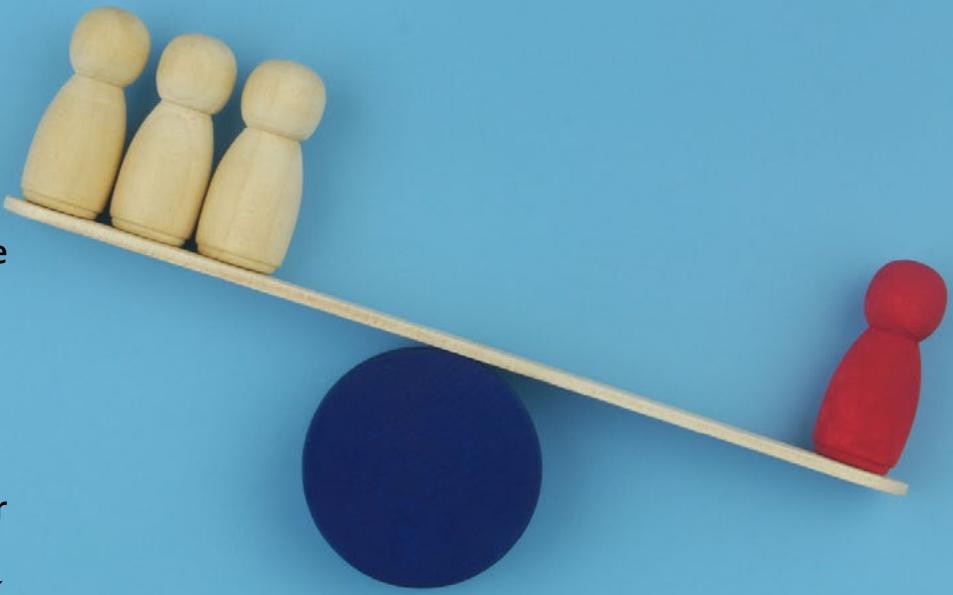


As the demand on the NHS continues to increase, it's imperative that the oncology workforce in the UK is equipped with the expertise, skills, and resources to deliver high-quality, patient-centred care. Health Education England continues to invest in the education and training of the NHS' oncology workforce, but pressures on healthcare services will continue to rise, necessitating expansion of the workforce to address both existing capacity challenges and growing demand.

To meet this growing demand, the NHS needs a workforce with capacity to support clinical research and patients in clinical practice. Building an oncology workforce fit for the future will require even greater collaboration between healthcare professionals, healthcare system decision-makers, industry leaders, policymakers, and patient communities. We spoke to experts at MSD and Prostate Cancer UK about some of the challenges that need to be addressed.

Continuing to tackle health inequalities

Every year, over 90,000 people in the UK are diagnosed with a less survivable cancer, such as lung, pancreatic, liver, oesophageal, stomach, and brain cancers. Deaths from less survivable types of cancer account for over 40% of all deaths from disease in the UK and contribute up to a quarter of all cancer diagnoses.





David Long, head of oncology at MSD, recalls a report published by MSD, with input from the Less Survivable Cancers Taskforce,

on inequalities in treatment and outcomes of less survivable cancers: "In order for the recommendations of this report to be realised, we require a workforce that has the capacity to address health inequalities, be it from a workforce planning perspective or by ensuring members of the existing workforce are aware of how they can best support all patients." The NHS recognises that people from lower socioeconomic areas have increased risk of cancer, increased risk of late-stage diagnosis, and have poorer prognosis, Long says, "It's important the oncology workforce is fit for the future – especially when it comes to less survivable cancers."

Chronic understaffing is widely acknowledged in disciplines such as oncology, radiology, pathology, and nursing, roles that are integral in ensuring all patients with cancer receive high-quality care. The strain on NHS cancer services is also recognised by the UK public, with 79% of surveyed people agreeing that the NHS lacks adequate staffing and resources to consult, test, and treat all patients with cancer effectively.

"The workforce shortfalls must be addressed by both additional recruitment and by supporting healthcare professionals already within the oncology workforce to work to the best of their ability," says Long. "Reducing the administrative burden on clinical roles needs to be prioritised through expanding the number of non-clinical roles within the workforce – for example, recruiting pathway navigators. This would give the clinical staff more time to support the increasing number of newly diagnosed patients to access innovative treatments as soon as possible."

Keeping the patient experience at the heart of oncology research, development, and healthcare

Developments in prostate cancer continually shift the demands on the workforce. But with the number of patients diagnosed only expected to grow, it's essential that the workforce is able to deal with this increasing workload in the future, allowing them to give the personalised and consistent support that makes a huge difference for patients.





Joseph Woollcott, policy & health influencing manager at Prostate Cancer UK, says, "We know that clinical nurse specialists (CNSs) are

key to patient experience and outcomes, and men who have access to a CNS consistently report a better experience. To maintain this high standard of care, we need a systematic, proactive approach to recruitment, training, development, and retention of nurses and other staff. To support this, we offer a range of health education and are aiming to publish a new professional framework later this year to make the career path for junior nurses more transparent and accessible, while reducing variation in services across regions."

"But without a comprehensive strategy to address shortages and future-proof the entire cancer workforce, frameworks like this won't be enough. That's why we're working closely with other charities as part of One Cancer Voice to call on the government to take concrete steps to address this issue, so cancer patients get the care and support they need now and in the future."



Prioritising collaborative relationships between the NHS and pharmaceutical industry in the here and now

Partnerships between pharmaceutical companies and the NHS can streamline the patient pathway to help enable patients to access treatment sooner.



MSD is working closely with the healthcare system to improve the time between diagnosis and treatment of cancer. **Rachel**

Houlding, national healthcare lead for oncology at MSD, says, "Better planning ahead and support for healthcare staff is required to enable the NHS to adopt innovations of the future."

MSD continues to work with Cancer Alliances and NHS Trusts by mapping out cancer care pathway challenges and solutions. For example, MSD hosted a capacity workshop with a Trust and Cancer Alliance, which helped 140 patients. This demonstrates the profound benefits of bringing together the NHS and industry to improve patient care.

Diversifying clinical trials to ensure cutting-edge medicine reaches patients sooner

Patient access and recruitment into clinical trials in the UK has been slowly declining. Participation in phase 3 clinical trials in the UK, between 2017–2021, decreased by 48% and the number of cancer clinical trials initiated in the UK per year has also decreased, by 41%. Research from 2020 in the UK indicated that 63% of patients with cancer would consider receiving treatment as part of a clinical trial, yet many are missing out on enrolment due to lack of awareness.





Christoph Hartmann, director for medical affairs at MSD, says, "We need to improve the accessibility of clinical trials for

patients with cancer and ensure that clinical trial designs comprise a diverse population, including people with different protected characteristics." Hartmann added, "With great progress being made in oncology therapeutics research and advancements in technology, the existing systems and structures used for data collection are increasingly inadequate."

For example, the time and cost implications of enrolling patients into some clinical trials could be reduced if the biomarker status of patients was accessible in a centralised database. These possibilities emphasise the need for accurate, standardised national data on cancer patients.

"To deliver both diverse and efficient clinical trials, we require a skilful workforce that is trained in conducting high-quality trials with a culture in the NHS that values them," says Hartmann. Lord O'Shaughnessy's recent review of commercial clinical trials recommended that the NHS should use the upcoming NHS Long Term Workforce Plan and UK Recovery, Resilience, and Growth (RRG) Research Workforce Strategy to establish a Clinical Trials Career Path for training critical research roles – realising this recommendation is essential to create an oncology workforce that is fit for the future.

Investing to expand the NHS workforce

Critical shortages in key staff and resources could be mitigated by implementing long-term strategic plans across cancer care pathways. The Royal College of Radiologists found there is currently a 15% shortfall in clinical oncologists, which is projected to increase to 25% by 2027, and a 29% shortfall in radiologists. As a result of shortages, treatment is being delayed.

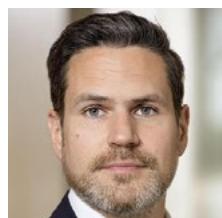


Harriet Adams, director of oncology policy and communications at MSD, says, "MSD recognises the acute need for an

NHS Long-Term Workforce Plan, alongside the funding required to implement its recommendations. Not only is this critical for outlining the needs of the future oncology workforce, but also in enabling capacity building within the existing workforce."

"While there is more to do, we will continue to work with others in the cancer community to address the challenges the NHS workforce faces because we know we are stronger together. Ultimately, through our work at MSD and collaborations with healthcare services and cancer charities, we believe we can help to redefine what survival means for cancer patients – finding ways to give people not only more time, but better quality of life in the time they have."

About the authors



David Long is head of oncology at MSD



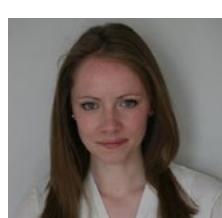
Joseph Woollcott is policy & health influencing manager at Prostate Cancer UK



Rachel Houlding is national healthcare lead for oncology at MSD



Christoph Hartmann is director for medical affairs at MSD



Harriet Adams is director of oncology policy and communications at MSD

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Pharmaconex
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2nd Global Conference on Pharmaceuticals and Clinical Research
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Events details

Europe

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GIANT health
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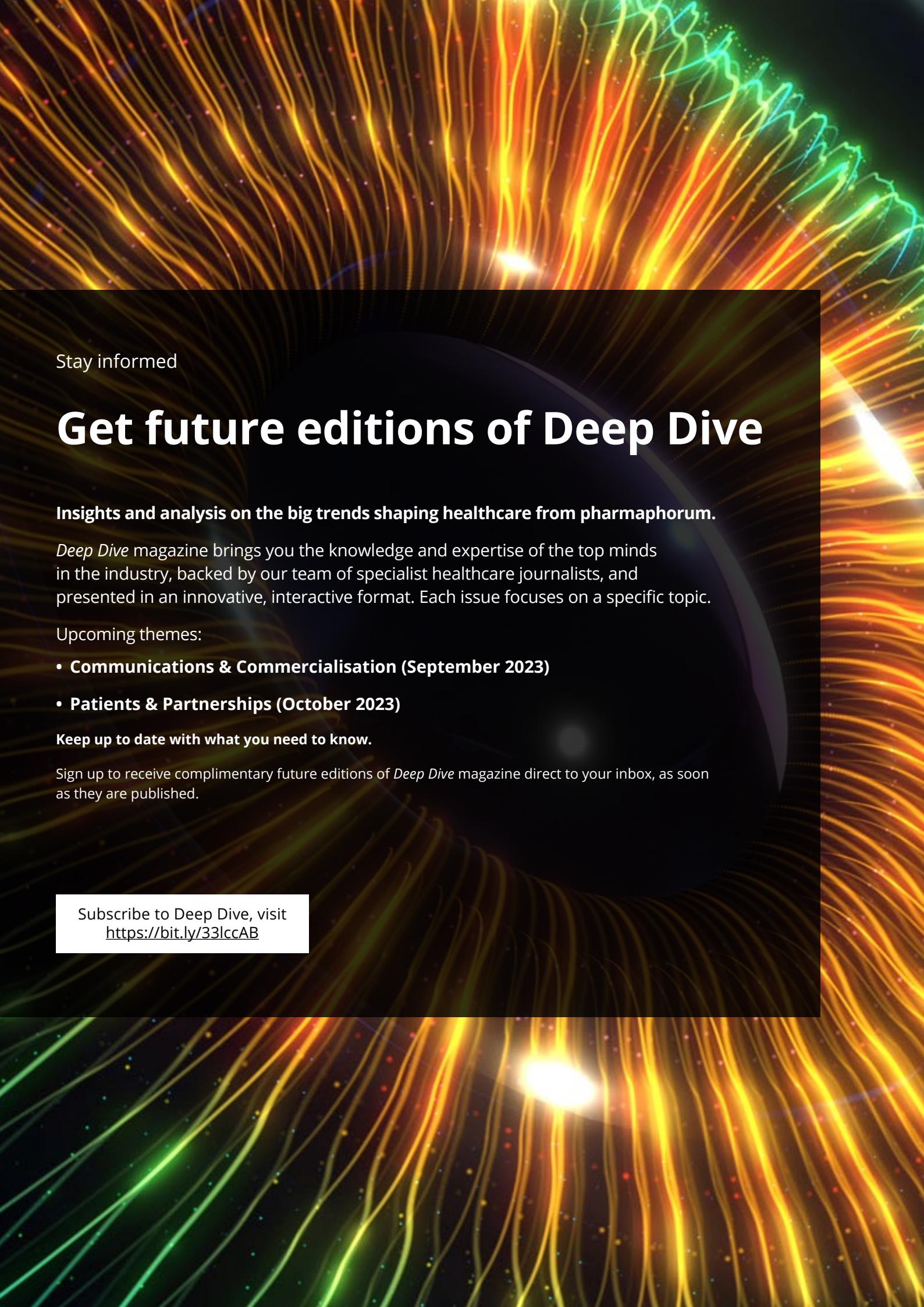
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81st FIP World Congress of Pharmacy and Pharmaceutical Sciences
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