Commercialising innovative new medicines

OPEN HEALTH

As pharmaceutical ingenuity hits new heights, ensuring that patients gain access to innovative medicines requires a unique combination of evidence generation and communication

Working with all stakeholders to generate evidence that communicates value, from early phase development to launch and reimbursement, is essential in therapy areas including oncology.

These are challenging times for the pharmaceutical industry as it navigates an oncology landscape offering an increasing array of new ways to target and treat cancer.

The rise of ever-more personalised treatments for different tumour types, a greater understanding of the mutations that cause cancers and the increasingly central role of combination therapies are just some of the factors that make this a particularly complicated and competitive space.

Consequently, there is a greater than ever need for pharma to partner with agencies whose multidisciplinary teams understand the clinical aspects of advanced technologies, in oncology and other therapy areas, have the methodological expertise to address those challenges, and can also have those discussions from a commercial and marketing perspective.

Geographic Reach

700+ people in 15 locations across 6 different countries including the US, the UK, the Netherlands, Germany, India and China

Clients

200+ current sponsors

Working with 90% of the top pharma brands

Publications

1,200+ peer-reviewed publications

Core areas of expertise

- Real-world evidence and data analytics
- Patient-centred outcomes
- Modelling and meta-analysis
- Strategic market access
- Multichannel medical education
- Publications planning and delivery
- Internal training
- Patient engagement
- Patient and brand communications
- Digital and creative

Therapeutic focus

Experience in a wide range of therapy areas, including oncology, endocrinology, rare disease, cardiology, neurology, pulmonology and genetics

Our mission

Improving the lives of patients, worldwide

The integrated group of practices at OPEN Health were brought together to meet these needs through a suite of services aimed at identifying and addressing evidence gaps and delivering world class value communications across a wide range of media.

"Commercialisation of new technologies in oncology requires expertise in both health economics and outcomes research (HEOR) and medical communications," says Dorinda Hickey, joint managing director at OPEN VIE. "Development of a compelling value proposition supported by robust evidence generation planning is essential in order to be able to communicate value, demonstrate cost-effectiveness and secure patient access to treatment.

"In the absence of randomised controlled trial evidence due to small patient numbers, it is important to be able to demonstrate incremental clinical benefit and value using real world-evidence, health informatics, modelling and meta-analysis to capture not only clinical endpoints, but also economic and humanistic outcomes.

"Real world-evidence, health informatics, modelling and meta-analysis are key levers that pharma needs to gain positive health technology appraisal outcomes. Data collection over the long term, particularly through patient registries or retrospective analyses, is often also needed to demonstrate an overall survival benefit as proof that the surrogate markers used for health technology assessment (HTA) are adequate."

Pharma's key oncology needs in HEOR and medical communications

For over a decade, oncology has experienced a sustained period of scientific innovation that has seen the emergence of personalised treatments and immuno-oncologics that train the body's own immune system to fight a tumour, and cell and gene therapies. Together these advances make oncology a hugely exciting therapeutic area.

But, as the nature of oncology innovation becomes ever more complex, so too does the task of proving the worth of new and innovative medicines, particularly when it comes to first collecting the necessary data to support a drug during HTA discussions and then communicating those outcomes to healthcare professionals.

It's not enough to just release new data and hope that it will make its mark in a clinical world that can often be overwhelmed with new study readouts to digest.

"Companies need to be actively publishing their data and assisting healthcare providers and payers in understanding the complex data and evidence generation methodologies behind it," says Dorinda. "It's important that the industry can simplify and explain all of the different technologies and methodologies that are used, so that the value messages for products resonate with clinicians."

Aside from randomised controlled trials, evidence generation methodologies used for HTA submissions and value communications include observational research such as primary data collection including patient surveys, medical chart reviews, or registries and secondary data analytics, systematic literature reviews, meta-analysis and health economic modelling. Patient-centred methodologies including qualitative interviews, social listening exercises, and patient preference studies can help contribute to the interpretation of this data from a patient's perspective.

Rosemary Jose is director of strategic market access at Pharmerit – an OPEN Health Company, and she explains how the expanded OPEN Health Group, which merged the medical communications business of Peloton Advantage in 2018 and Pharmerit's HEOR and market access business to the group earlier this year, can also assist with the communication element of pharma's data needs in oncology.

"What the medical communications team offers is excellence in publication planning, which pharma increasingly needs to use earlier in the product life cycle. Strategically planning which conferences and journals to target, and when to do so should be done in parallel with the HEOR activities. Being able to do both of these, through OPEN Health's mergers with Peloton and Pharmerit, allows us to be a strategic partner for HEOR and medical affairs along the product life cycle."

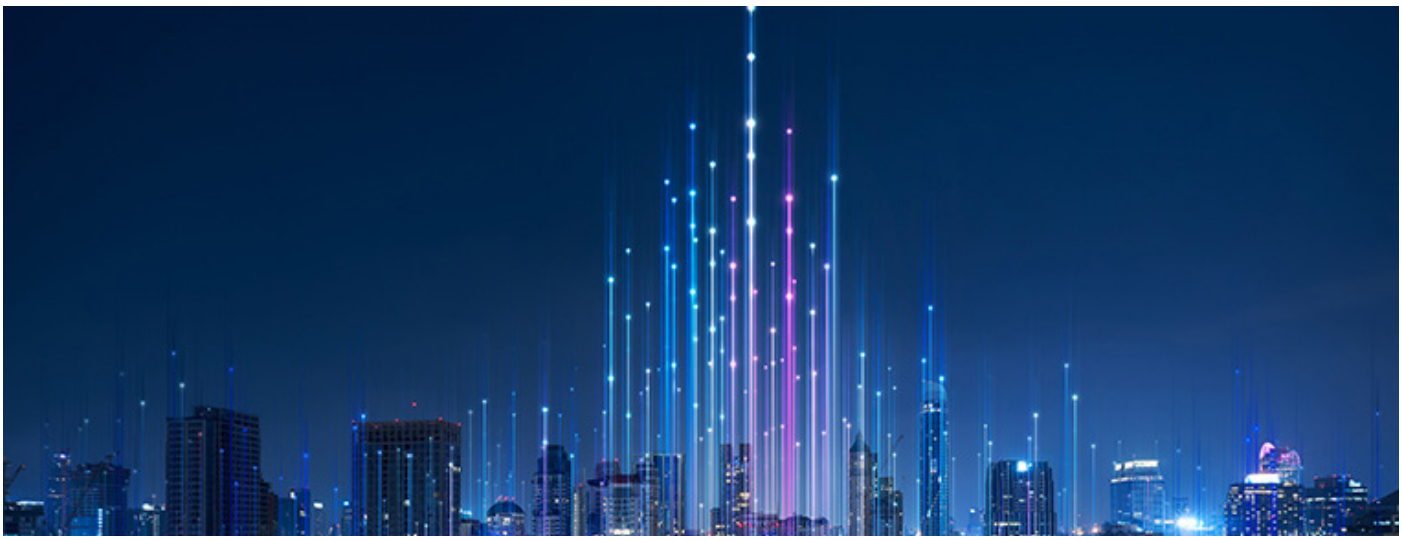
Marja Hensen, director of strategic market access at Pharmerit – an OPEN Health Company, adds: "Education and training are equally important. We do not stop at delivering the evidence, publications or communication tools. We train the stakeholders to effectively get the message across. Especially in the field of innovative oncology, where clinical trial data can be limited and innovative methodologies are increasingly used to demonstrate value, this becomes even more important in the future."

The effective communication of evidence and outcomes that the company can deliver is an important asset to its clients – in oncology as well as in other therapeutic areas. The way that the group's HEOR solutions solutions apply complex and innovative methodologies to evidence generation and cost-effectiveness demonstration, and then combine them with effective expertise in medical communications, is hugely valuable for pharmaceutical companies. It has proven benefits in successfully explaining what new innovations mean for medical practice and how they can benefit patients.

Cross-border HTA considerations

Beyond healthcare professionals (HCPs), payers constitute another key stakeholder for pharmaceutical companies, and they're a group that pays particular attention to innovation in therapy areas like oncology, where big therapeutic advances often require major financial investments.

In looking to meet payers' needs, one of the areas in which a strategic approach to market access is necessary relates to cross-border considerations. Different countries' pricing and reimbursement systems, whether through direct price referencing or the influence of high profile HTA bodies like Germany's IQWiG and NICE in the UK, are increasingly interconnected. At the same time each country also has its requirements that add up to a complex global HTA environment, with local nuances, that brings with it clear considerations for pharmaceutical companies about the kinds of companies with which they should partner. It takes a multidisciplinary team to understand the market, be able to deliver and interpret the science, and provide strategic support around the comprehensive value of therapies.



"Geographical expertise is extremely important because, although the strategy is often driven from the top down or cascaded down from the global team, every market has different requirements. A strategic partner should have an idea of how a global cross-functional team works and also understand what the local markets require," says Rosemary.

On an individual level, payers may need their own cost-effectiveness studies, comparative clinical effectiveness research or budget impact analyses, but there's also a trend for countries to go beyond reference pricing models of influence to direct collaborations around stronger price negotiation or managed entry agreements and value based pricing. We also cannot ignore joint clinical assessments that are being conducted through the EUnetHTA initiative, as discussions continue about how HTA in Europe can be harmonised. Moreover, as there is a movement towards greater patient centricity worldwide, it is important to have experts who understand how to engage with patients as champions of their own condition in the drug development, approval, and commercialisation process.

"This is what makes OPEN Health a strategic partner – the fact they recognise the nuances of how these different requirements can be met and how we can develop that one common dossier or submission that addresses everybody's needs, and how to address the challenges this approach might create," Rosemary adds.

Strengths of the combination of OPEN Health, Pharmerit and Peloton

Tackling the evidence, communications and access environment for commercialising innovative new medicines demands a special type of agency partner, and the new combination of OPEN Health, Pharmerit and Peloton has some key differences from other HEOR companies or med comms agencies.

"With the skills to cover the whole development process from early phase research through to launch and reimbursement, we provide a full-service offering in the commercialisation process for innovative new medicines, working with all stakeholders, physicians, patients, and payers, communicating the value of new treatments, and securing positive health technology appraisals and system funding," Dorinda explains.

The integration of Pharmerit into the group earlier this year has strengthened its global footprint as well as the range of its core capabilities, from health economics and real world evidence to patient-centred outcomes to strategic access reimbursement and medical affairs supported by digital communications.

As Rosemary notes: “We can do so much more as a single combined entity. On the one hand, there are synergies across the strategic market access teams, where we can work cohesively to generate compelling value propositions. On the other hand, complementary elements have come together, for example, of value communications with digital solutions. Or for instance, publication planning, with a focus on health economics and outcomes research. Or, HEOR and market access with digital training solutions. The possibilities are endless.”

The company isn’t siloed – either across locations or teams, so it’s easy for different parts of the whole entity to come together for a particular project, bringing all of their specialist expertise and knowledge. The teams are working in an integrated way across different specialties/centres of excellence and many consultants have experience working across different types of projects. The benefit this brings to pharma is that the group is able to look at the product’s evidence generation and communication with a bird’s-eye view, making it a truly strategic and global partner.

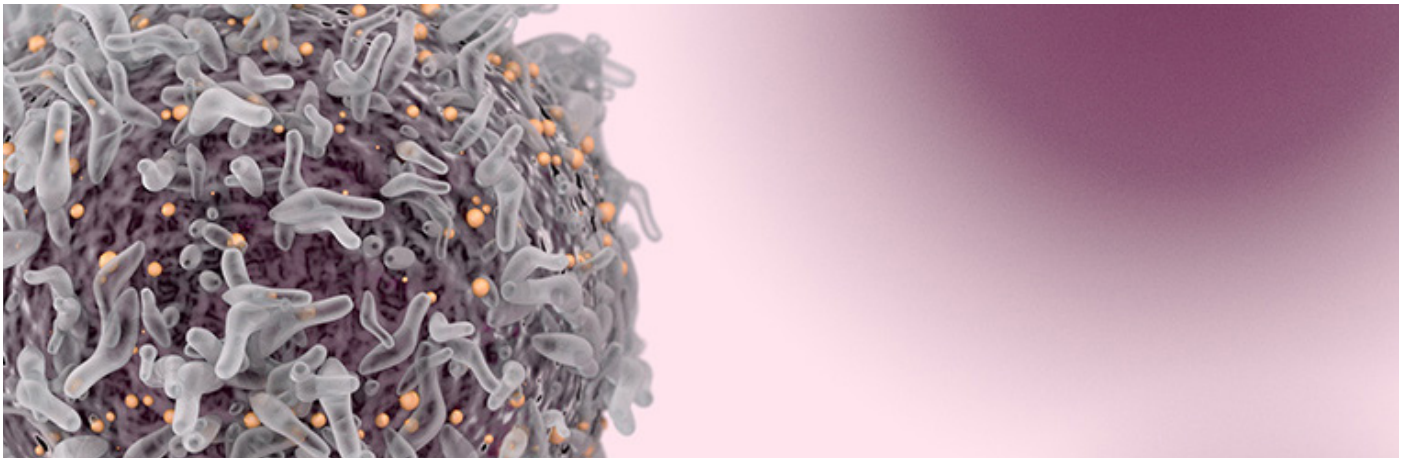
Dorinda explains: “We work a lot with different patient groups to make sure that they have a voice and that they can get access to new and innovative treatments. Our work on HTA submissions, for instance, may involve long-term follow-up of patients to prove that, for example, gene therapies and cell therapies actually work. So, we’ve seen first-hand the importance of working not only with patients to generate data but also as co-creators to ensure that, at the stage of reassessment, these products continue to be funded.”

Mapping the patient journey in melanoma and Hodgkin’s Lymphoma

Patient journey studies have been one of the areas where the combination of OPEN Health, Pharmerit and Peloton has successfully contributed to improving patient outcomes.

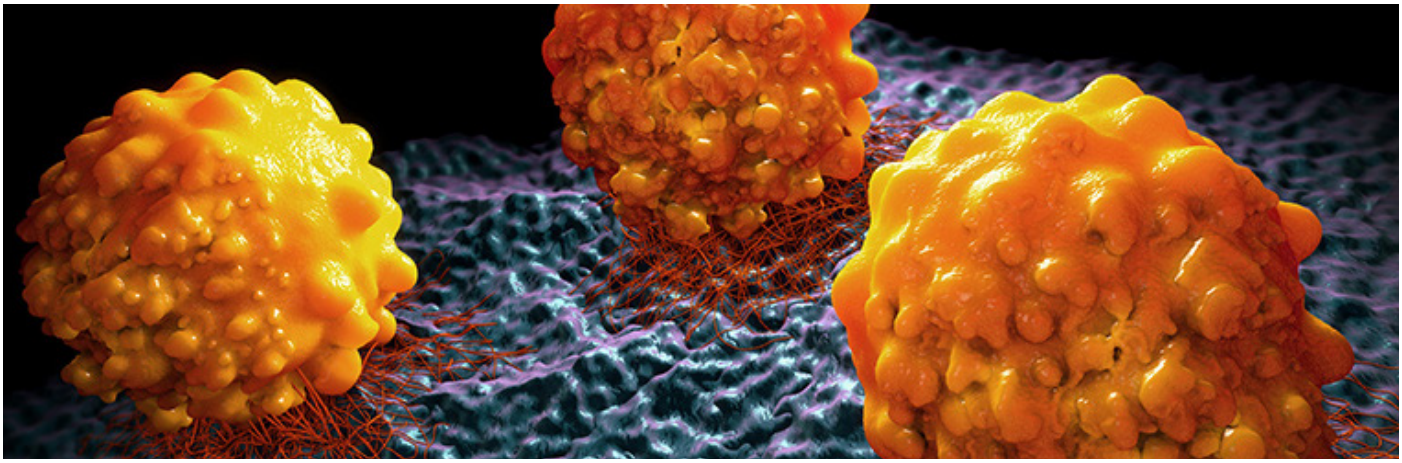
One case saw the Group working in melanoma to support HTA submissions to the Pan-Canadian Oncology Drug Review Committee (pCODR), which gives recommendations and evidence to the Canadian Agency for Drugs and Technologies in Health (CADTH).

pCODR had requested that the patient voice be included in the application for coverage for a product in advanced melanoma, but no quality of life data had been collected during clinical trials for the product.



To overcome this, OPEN Health worked to gain patient-centred descriptions of symptoms, disease and treatment burden, diagnosis/treatment journey and healthcare resource utilisation. This involved a literature review, an advisory board with KOLs, clinicians and patients, a series of in-depth interviews with patients, caregivers, healthcare professionals, and finally the coding and analysis of the interview transcripts.

This comprehensive approach made it possible for the sponsor to successfully submit new data to pCODR showing that its product aligned with patient values.



Meanwhile, in a separate study OPEN Health illustrated the global patient journey in Hodgkin's Lymphoma (HL), illuminating the emotional journey for HL patients, carers, and HCPs from pre-diagnosis to treatment maintenance in three different markets.

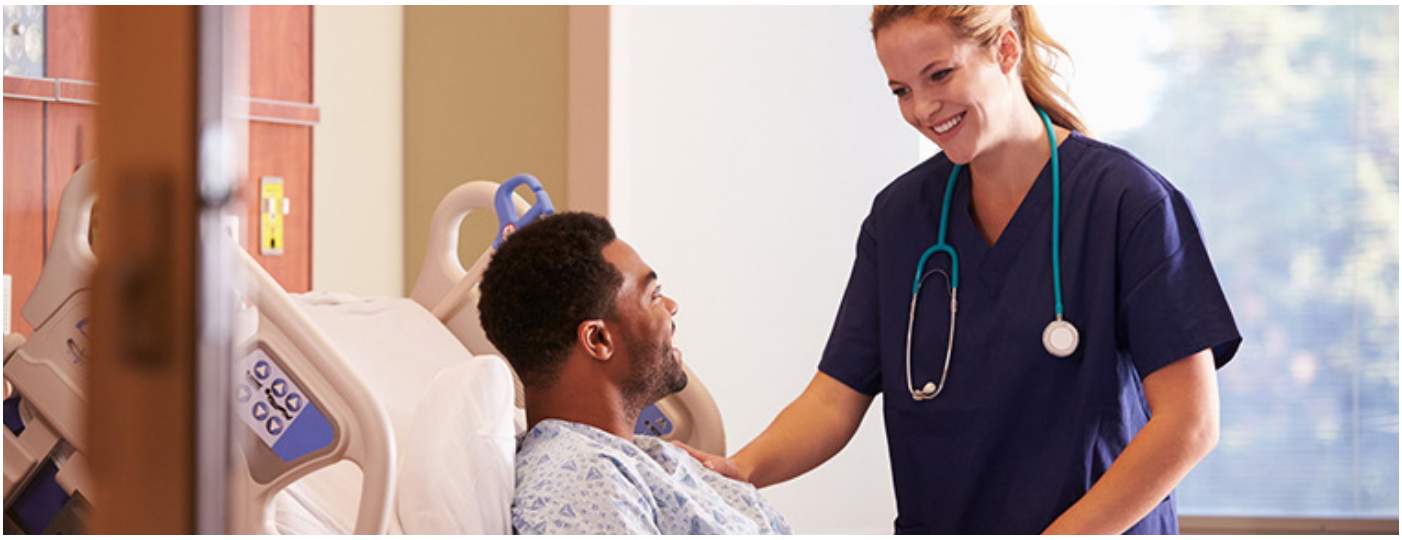
To do this, OPEN Health produced a visual and easy to understand mapping of the patient journey in HL that highlighted the emotional dissonance between treatment stakeholders, as well as simplifying and bringing clarity to the treatment journey for HL patients, carers and HCPs.

The interactive resource identified the unmet needs, key leverage points and tactical solutions around which new services could be developed to improve patient care, support HCPs and ultimately improve real world outcomes.

The sponsor was able to leverage this new knowledge to achieve a competitive advantage by developing differentiated tools and services to support patients and HCPs and the Patient Journey Map was used as the primary business planning tool.

Working to improve patients' lives

OPEN Health works closely with many different patient groups to make sure that they have a voice and to help them to gain access to new and innovative treatments. This can involve including their voice in discussions about payment mechanisms or long-term follow up, for example, gene therapies and cell therapies to build a body of evidence showing they work.



To do this the growing OPEN Health Group can call upon a combination of medical communications, publications planning, real-world evidence, health informatics and data analytics using artificial intelligence. As Dorinda notes: "We have a combination of engagement skills across physicians, payers, and patients, supported by digital expertise, which bring complex ideas about innovative medical treatments to life and makes them meaningful and easier to communicate."

About the interviewees

Dorinda Hickey is joint managing director of OPEN VIE. She has over 15 years' experience in market access consulting; specialising in pharmaceutical pricing and reimbursement, healthcare policy analysis, clinical advocacy, payer engagement and value communications. Prior to consulting, Dorinda spent many years in the pharmaceutical industry where she held positions in sales, marketing and market access including business unit and country management.

Rosemary Jose is director in the Strategic Market Access Center of Excellence at Pharmerit, and is based out of the Rotterdam office, the Netherlands. Rosemary has over 14 years of experience across the pharmaceutical industry, including more than 12 years in market access and health economics, both in global and consulting roles – leading strategic projects, managing international clients and mentoring multi-cultural teams.

Marja Hensen is director of strategic market access at Pharmerit. She has presented work at conferences including ISPOR, EFIC, ESH and EHA. Marja authored articles in Expert Review of Hematology, Diabetes Research and Clinical Practice, Haematologica and Applied Health Economics and Health Policy. She holds a MSc degree in Biomedical Sciences from the University of Leiden. She joined Pharmerit in 2006 and since then performed and led a large number of projects.

About OPEN Health

OPEN Health is a family of expert practices working in partnership to drive positive change in healthcare communications and market access globally. It all started with a vision for improving the lives of patients, worldwide. The OPEN Health vision has manifested with the integration of experts from Pharmerit and Peloton Advantage to create a new unique entity equipped to be a global leader in HEOR, market access, medical and patient brand communications and digital services.

For more information visit:

OPEN Health Group ›