pharmaphorum deepdive

Henrietta Lacks: A legacy of life

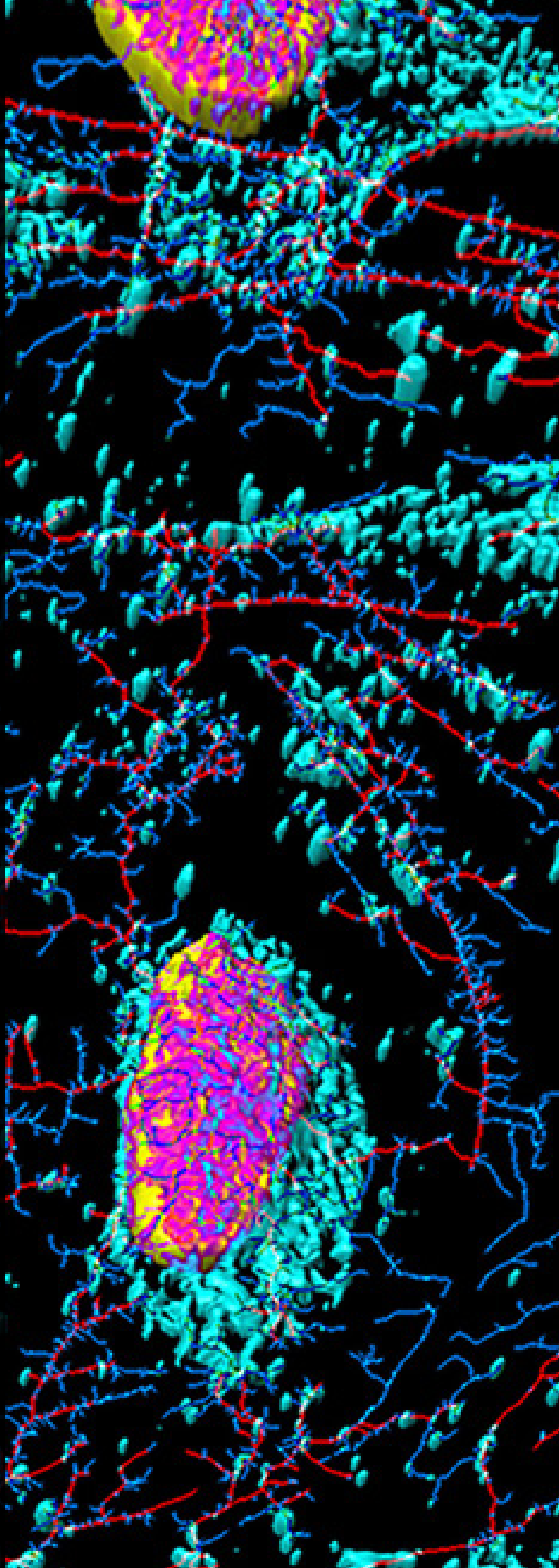
Inside one ordinary woman's unexpected contribution to medical research, and her family's ongoing fight to reclaim her story

October 2023: Patients and Partnerships

What If: Amplifying the patient voice through poetry

The evolution of active patient inclusion in trials

Combining patient and healthcare provider engagement strategies to optimise business and health outcomes



Contents

Deep Dive: Patients & Partnerships 2023

Consent has long been a controversial and complex debate for pharma. While the industry has actively placed great emphasis on efforts to promote the patient voice as the heart of development efforts in recent years, the role and rights of patients in medical research have not always been so clear-cut.

Perhaps the most famous example of patient consent in healthcare is the extraordinary life of Henrietta Lacks and her family's fight to reclaim her legacy. Following the historic settlement won by the Lacks estate earlier this year, we explore how one ordinary woman's cells changed the course of medical research, and the implications for patient rights and the commercialisation of life-saving innovations.

Beyond the HeLa controversy, we venture into the modern age of patient partnerships, as Pfizer moves toward sharing clinical trial participants' own data with them. Plus we learn how Lumanity combines patient and provider engagement strategies to optimise business and health outcomes, and examine the evolution of active patient inclusion in trials with the National Institute for Health Research.

As we immerse ourselves in these stories, debates, and partnerships, we invite you to join the conversation. Your thoughts, reflections, and perspectives are invaluable in shaping the ongoing dialogue about the intersection of healthcare, ethics, innovation, and the evolving landscape of patient engagement.

Wishing you enlightening reading.

Eloise

Eloise McLennan – editor, Deep Dive

Next issue:
Digital Health (November 2023)
Plus:
• Highlights from Frontiers Health

Catch up on recent issues:
Communications & Commercialisation – September 2023

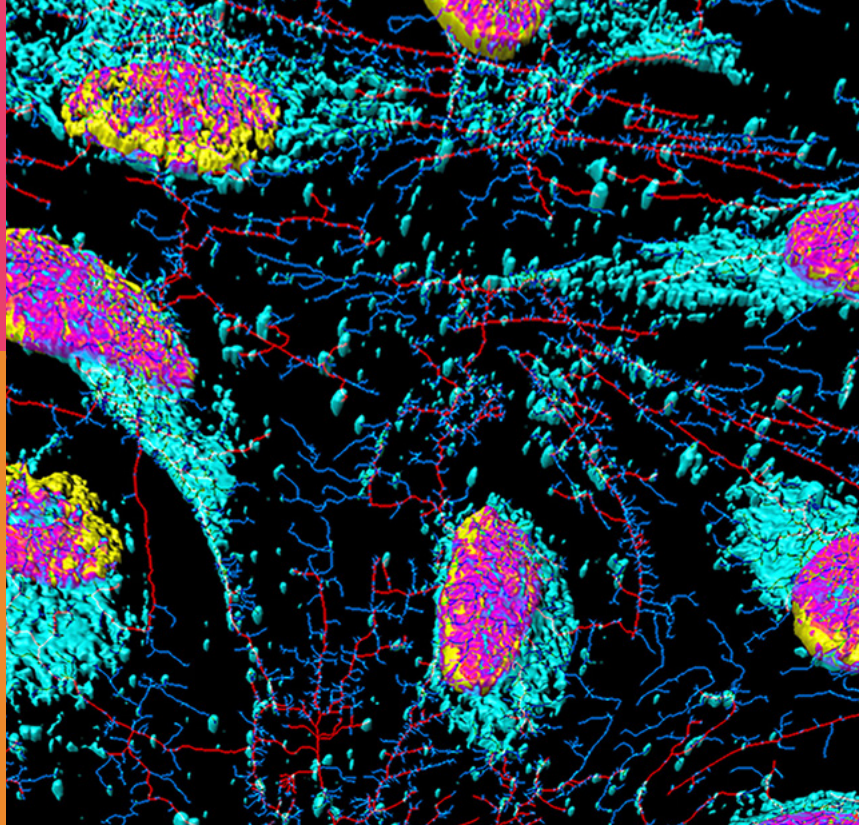
Market Access – April 2023

Research & Development – February 2023

Digital Health – November 2022

Patients & Partnerships – October 2022

Henrietta Lacks: The mother of modern medicine



In recent years, much attention has been given to the subject of patient rights; be this in the form of patient-centricity efforts, which place the individual at the heart of research and treatment efforts, or through the growing accessibility of healthcare information online.

Perhaps the most famous case of patient rights can be found in the cautionary tale of one seemingly ordinary woman, and her family's decades long fight for justice.

No one, bar her doctors and lead researchers, were privy to the origins of her cells, not her name, age, nor any details about her life. While her 'immortal' cells would enable researchers around the world to conduct experiments that could not be tested on living humans – driving decades worth of innovation – it would be two decades before the mystery of Henrietta Lack's identity would be revealed. And even more years before her surviving family would get answers.

The story begins – as so many do – with a patient walking into a hospital, looking for help.

1951

The woman behind the cells

Henrietta Lacks was just 31 years old when she walked through the doors of Johns Hopkins hospital. It was the only hospital around that would accept her as a patient. Segregation was the norm and, as a poor black woman living in the 1950s, Henrietta's options were limited.

She was a tobacco farmer, but had moved to Turner Station in Baltimore with her husband and two young children, having heard promise of greater fortune from those working in the area.

A year before her official diagnosis, Henrietta began to suspect something was wrong. She shared her worries with her cousins, saying that there was a "knot inside" of her. Her cousins tried to convince her to see a doctor, but Henrietta didn't, and a week later she discovered she was pregnant. She carried her baby to term, but every after birth, she still didn't feel right. On a referral from a local physician,

Henrietta went to John's Hopkins hospital to seek answers. On 29th January 1951, she and her husband made the 20-mile journey to the hospital, which was also a renowned research centre.

Dr Howard Jones, the gynaecologist on duty, examined Henrietta, and found a solid lump, about the size of a nickel, exactly where she described. The tumour was nothing like Jones had ever seen before (or would see again according to a later interview). It was as his notes described, like "grape Jello".

The appearance of the tumour was perplexing; Henrietta had recently given birth, and yet there was nothing about any abnormalities in her medical history. Surely someone would have noticed a tumour that size during her pregnancy? The only conclusion was that the tumour must have developed at a rapid speed – not a good sign.

"Henrietta Lacks" by Oregon State University is licensed under CC BY-SA 2.0 .

He cut a tiny biopsy of the tumour to confirm that it was indeed cancerous. Then he sent Henrietta home to await the results. A few days later, confirmation came "Epidermoid carcinoma of the cervix, Stage I."

In 1951, it was standard practise to conduct medical research on public ward hospital patients without their consent, mostly viewed as a quid-pro-quo exchange for receiving free healthcare. Informed consent wasn't a term that was coined, so no legal or ethical standard existed in the US for obtaining it. At Hopkins, the leading cervical cancer expert, Richard Telinde, believed it was a payment for services.

Without Henrietta's knowledge, a sample of her tumour was sent to the nearby lab of Dr George Gey, the head of tissue culture research at Hopkins. For years, Gey had been trying to grow and keep alive human cells outside of the body in petri dishes, but to no avail.

Henrietta, meanwhile, was treated with radium, an astoundingly radioactive element that, if delivered in high enough doses, can actually cause cancer. At first it appeared to be working, but soon enough, more and more tumours began to appear throughout Henrietta's body, and she was in immense pain. Although doctors tried to ease her suffering, it was no use. And at 12.15am on the 4th of October 1951, she died in her hospital bed. Her body was returned to her home in Clover, where she was buried in her family plot, in an unmarked grave next to her mother.

Life after death

By the time Henrietta walked into the hospital, Gey's assistant, Mary Kubicek, had already spent countless hours studying the cell cultures sent to the lab for analysis. None had survived. So, when a seemingly innocuous new arrival appeared on her desk, she had no reason to suspect this culture would be any different from those that had come before.

Pushing aside any initial misgivings, she diligently set to work slicing the cells, preparing the culture medium, and marked the samples the same way she had labelled most cultures, using letters from the patient's first and last names: HeLa.

When Mary returned the next morning, she was surprised to find that Henrietta's cells had multiplied, and they kept multiplying at an astonishing rate, expanding into as much space as Mary would give them.

This was – to say the least – highly unusual. Ecstatic, Gey described the cells as growing "like crabgrass". Soon enough, he began to share the discovery of these 'immortal' cells with some of his closest colleagues. And when these confidents requested samples for their own studies, Gey happily obliged.

Mass distribution of live cell cultures via mail wasn't exactly a common practise at the time. So, instead Gey opted to transport the HeLa cells by plane. But, as demand for the cells grew, it became evident to all that a new distribution system was sorely needed. And so, in 1952, Gey experimented with a handful of tubes containing HeLa cells, which he packed into a tin lined with cork and ice and shipped to Minnesota. Freezing the cells turned out to be a resounding success, and marked the first instance of live cells being successfully shipped in the mail.

By Preservation Maryland – Turner Sation, Henrietta Lacks House, CC BY-SA 2.0, https://commons.wikimedia.org/w/index.php?curid=47624579

That same year, only a few months after Henrietta's untimely passing, her cells would further cement their importance in medical history, when American virologist Jonas Salk put out a call to culture experts to help find samples for a large-scale test of his newly developed polio vaccine. For Gey, it was a valuable opportunity: HeLa was a perfect fit for testing the vaccine.

The infamous Tuskegee Institute was chosen to house a new HeLa Distribution Centre. With William Scherer from the National Foundation for Infantile Paralysis at the helm, the Institute steadily expanded operations, producing a whopping 25,000 tubes of HeLa every week.

Soon enough, surging demand for HeLa cells overwhelmed the production line at the Tuskegee Institute. In an abandoned Fritos factory, a new microbiology company was established to accommodate the need for HeLa. It was a flurry of excitement and innovation for the scientific community. But, while her cells quickly found their way into labs around the world, available for scientists to buy for roughly ten bucks a pop, Henrietta's real name, her life, and her legacy was left behind.

1960s

To infinity and beyond

Continuing HeLa's streak of pushing scientific boundaries, in 1964, they became passengers on some of the first capsules to explore outer space. In the second satellite orbit ever, scientists used HeLa cells to understand the effect of space travel on the body. The experiments showed cardiovascular changes, bone and muscle degradation, and a loss of red blood cells. Moreover, HeLa revealed that cancerous cells divide faster with each trip, unlike the non-cancerous cells that grew normally.

Back on Earth, the decade proved to be something of a mixed bag for HeLa. Having witnessed year after year of astounding success, shedding light on treatments for blood disorders, helping researchers to understand the impact of X-rays, and playing a fundamental role in developing cancer research methods, the HeLa train was chugging along at top speed. That was, until 1966, when geneticist Stanley Gartler took to the stage at a conference for cell culture scientists and, in front of George Gey himself, delivered what would later be dubbed the 'HeLa bomb'.

During his presentation, Gartler revealed that the 18 most commonly used cell cultures shared a rare genetic marker, only found in a small minority of Black Americans. Having received confirmation of Henrietta's race only a few short months prior, Gartler was certain that the presence of these rare cells in multiple cultures illuminated a serious 'technical problem' in the field of cell culture research. While the risk of contamination from bacteria and viruses was well understood, what researchers didn't know was that HeLa cells could latch onto skin, clothing, shoes, it could travel on dust particles and drift through ventilation systems. In short, they could easily contaminate and take over other cultures.

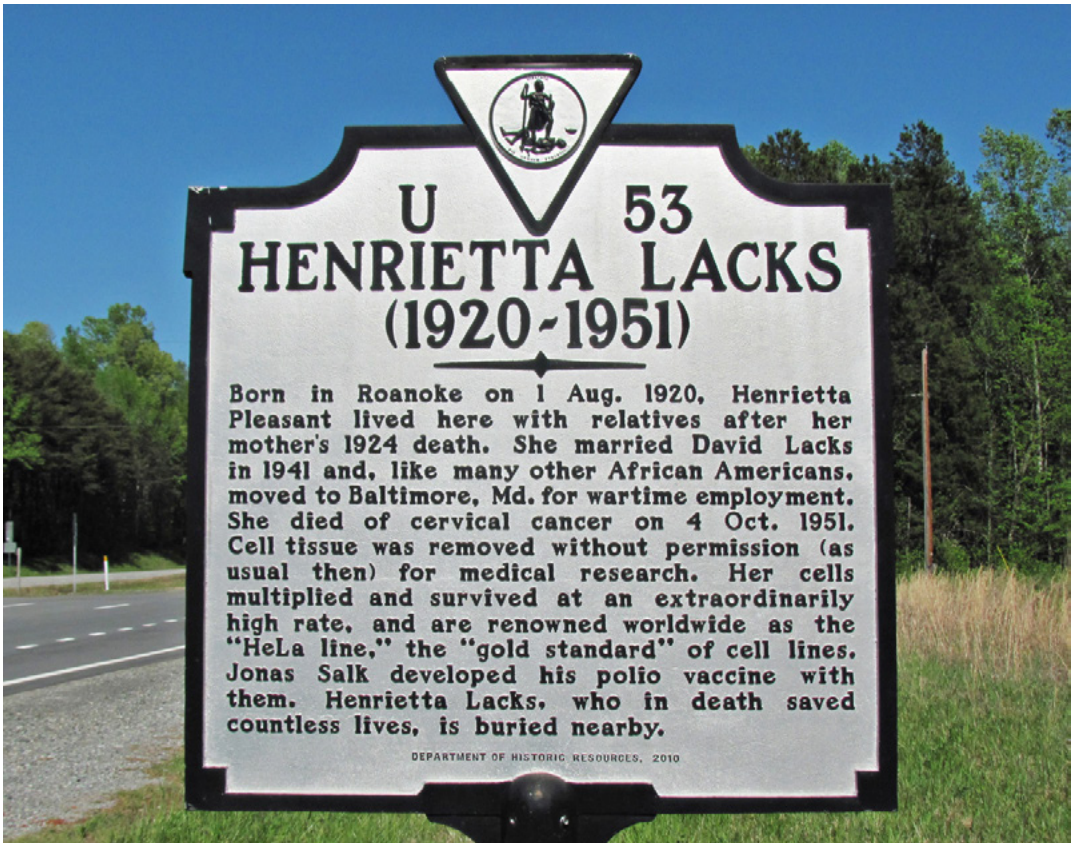


Image credit: David Hoffman, Henrietta Lacks (1920-1951) www.flickr.com/photos/universalpops/48749065998

His remarks had disastrous implications. If what he said was indeed true, millions of dollars in research would now be worthless. Unsurprisingly, his findings were met with a remarkable display of scientific hubris, with audience members opting to attack Gartler's competency, rather than heed his warning. But not everyone in the audience was so quick to dismiss the claim. Several researchers, including future president of the American Type Culture Collection, Robert Stevenson, began to test for the genetic marker in their labs – and, boy, did they find it. Realising the potentially devastating scope of the HeLa contamination, they set to work developing genetic tests to identify HeLa cells in culture.

It was these genetic tests that would eventually lead scientists to cross paths once again, with the unsuspecting family of Henrietta Lacks.

1970s

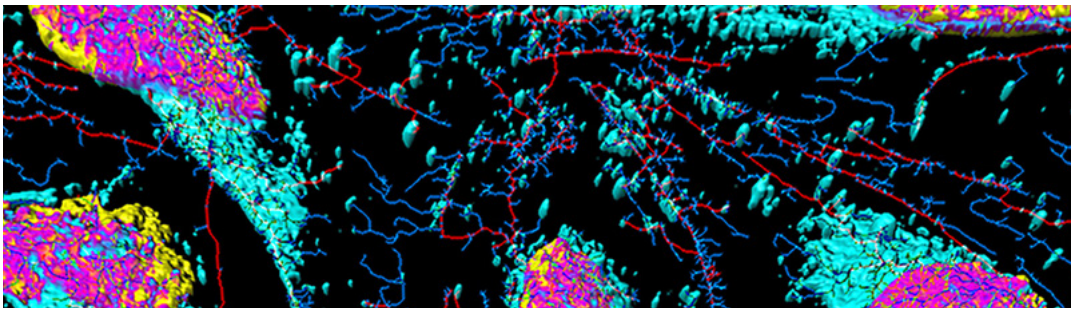
What's in a name?

Through his work with HeLa, George Gey had immortalised himself, but his mortal body was not to experience the same fate. Mirroring the final journey of his most famous patient, in 1970, Gey succumbed to an aggressive form of cancer, but not before he reportedly instructed his former assistance, Mary Kubicek, to reveal Henrietta's name, should anyone ask. She never did.

In an effort to pay homage to their former colleague, several doctors from Johns Hopkins penned an article dedicated to his work in ensuring the legacy of HeLa. To refresh his memory of the case, one of these writers – Howard Jones – decided to revisit Henrietta's medical records, including the photographs of her biopsy. Upon seeing the documents, Jones was sure that Henrietta had been misdiagnosed. To confirm his theory, he turned to a time capsule of sorts, which had sat undisturbed on a shelf, since 1951 – Henrietta's original biopsy sample.

When the tribute to Gey was finally published in 1971, the authors asserted that Henrietta's tumour had been 'misinterpreted' by the original pathologist, and in fact was not an epidermoid cancer, but stemmed from glandular tissue in her cervix. Although this revelation would not have changed Henrietta's treatment, or fate, the article did right one significant historical wrong. Henrietta Lacks was no longer anonymous, unknown, or even the misreported 'Helen Lane'. For the first time, her real name was there in print for the world to see.

Just three weeks after Henrietta's name was revealed, US President Richard Nixon's War on Cancer thrust HeLa back into the spotlight. In a story befitting a spy novel, a battle between contamination theory supporters and naysayers raged, with Walter Nelson-Rees hired by the National Cancer Institute to help curb the problem. During his tenure, Nelson-Rees became renowned as a persistent watchdog, publishing "HeLa hit lists" in Science, which listed any contaminated lines that he had uncovered. No warning, no mercy.



Elsewhere, news that Henrietta's cells had been taken, grown, and sold the world over had finally reached the ears of the surviving Lacks family. Unsurprisingly, they were not best pleased to learn what had become of the last surviving piece of their loved one.

Unaware that the Lacks family had any knowledge of HeLa, in 1973, researchers gathered to discuss the issue of contamination at the First International Workshop on Human Gene Mapping. During the discussions, it was pointed out that specific genetic markers could be used to identify which cells stemmed from Henrietta. The only problem was that this would require a DNA sample from a close family member.

For years, Henrietta's life had been deliberately separated from HeLa, but in 1973, that changed when researchers actively sought out family members to donate blood. What exactly was said to the Lacks to explain the situation is uncertain, nonetheless, Henrietta's relatives obliged. Findings from this research were later published, including personal medical information for the family members, an unthinkable action by today's standards.

But the more that the Lacks family learned about the development and commodification of HeLa, the more they questioned and contested the situation. There is no record that Gey or Johns Hopkins profited from HeLa, but many companies have. But what rattled Henrietta's daughter, Deborah Lacks most, was the repeated misnaming of her mother as 'Helen Lane'.

HeLa vs. HIV and HPV

As the Lacks family embarked on a journey of HeLa discovery, in clinical research labs throughout the 1980s the cell line continued to exert a profound influence on medical science, marking a pivotal era in the exploration of cellular biology and medical breakthroughs.

During this period, the human immunodeficiency virus (HIV) emerged as a global health crisis. HeLa cells played a crucial role in studying the virus's behaviour, offering insights that contributed to the development of diagnostic tests and antiretroviral drugs. Additionally, HeLa cells became integral to cancer research, aiding in the exploration of new therapies and treatment modalities.

Notably, in 1984, HeLa cells were used to uncover secrets from the very condition that led Henrietta to Johns Hopkins. HeLa cells served as a crucial testing ground for HPV vaccine candidates, facilitating the evaluation of their efficacy and safety. This research marked a significant stride towards the eventual introduction of vaccines designed to prevent cervical cancer, demonstrating the practical applications of HeLa cells in the pursuit of public health interventions.

Dr Francis Collins meets with family members of Henrietta Lacks at Johns Hopkins University in Baltimore where he delivered the keynote address of the Henrietta Lacks Memorial Lecture. From left to right: Devin Lacks, Alyana Rogers, Dr Francis Collins, Jabrea Rogers, and Dorian Lacks. Credit: Public domain, via Wikimedia Commons

However, the 1980s also saw heightened ethical scrutiny surrounding HeLa cells and the broader context of cell research. Questions of consent, privacy, and the commercialisation of biological materials became prominent ethical considerations. As HeLa cells contributed to vital advancements in understanding and combatting HPV, increased awareness of Henrietta Lacks' legacy underscored the importance of ethical guidelines in biomedical research, setting the stage for ongoing ethical discussions in the years to come.

The way of all flesh

By the 1990s, the story of Henrietta Lacks had travelled far and wide, until eventually it found its way across the pond, to the office of Adam Curtis, a producer at the BBC. Recognising the potential, in 1996, Curtis decided to create a documentary about Henrietta. For Deborah and her family, it is a unique opportunity to tell their side of the story. In addition to interviewing Henrietta's surviving family members, Curtis and his team descended upon Turner Station to learn more about Henrietta from those who knew her.

Around this time, efforts to get the state to recognise Henrietta ramped up. These attempts proved successful, with Maryland State Senate and the House of Representatives both publicly acknowledging and honouring Henrietta. But despite persistent requests to recognise Henrietta, Johns Hopkins refused to accept any accountability. Hopkins did, however, state that it never profited in any way from HeLa.

"Henrietta Lacks" by Crawford Brian is licensed under CC BY-SA 2.0 .

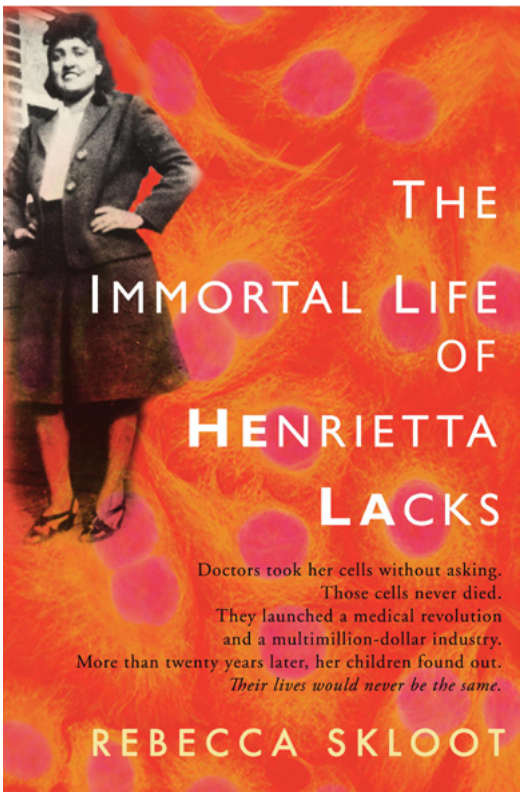
The publicity surrounding Henrietta and the HeLa cells fuelled ethical debates surrounding consent – and attracted some unwanted attention. Early attempts to pursue legal claims to Henrietta's legacy turned out to be a con scheme, concocted by a distant family relative looking to cash in on the family's ongoing struggle. Shortly after the plot was uncovered, the BBC documentary *The Way of All Flesh* aired. But the weight of the whole saga was too heavy for Deborah to bear, and the stress began to impact her health.

2000s

The immortal life of Henrietta Lacks

The 2000s witnessed a resurgence of significance in HeLa cell research, propelled by advancements in genomics, cancer studies, and the exploration of novel therapeutic avenues. Genomic research, fuelled by the Human Genome Project, leveraged HeLa cells to decode the human genome.

In cancer research, HeLa cells continued to be instrumental, aiding in the development of anti-cancer drugs and the exploration of innovative treatment strategies. Scientists utilised HeLa cells to understand the molecular mechanisms driving cancer progression, identify potential drug targets, and refine approaches to precision medicine.



"'The Immortal Life of Henrietta Lacks'" by Oregon State University is licensed under CC BY-SA 2.0 .

The 2000s also marked a pivotal moment in recognising Henrietta Lacks' legacy. The publication of Rebecca Skloot's The Immortal Life of Henrietta Lacks brought Henrietta's story to the forefront, sparking discussions about bioethics, patient consent, and the commercialisation of human biological materials. This renewed attention prompted initiatives to honour Henrietta Lacks and address the ethical implications surrounding the use of her cells.

Moreover, the decade saw a rise in legal challenges to stop the nationwide practice of storing and conducting research without consent. Plus, in 2006, a National Institutes of Health (NIH) researcher was charged with violating a federal conflict-of-interest law for providing thousands of tissue samples to Pfizer in exchange for about half a million dollars.

Who owns Henrietta's cells?

The 2010s marked a crucial juncture in the longstanding debate over ownership and control rights to the HeLa cell line. In response to growing concerns over consent and commercialisation, the NIH took steps to address the issue. In 2013, an agreement was reached between the Lacks family and the NIH, granting the family some control over access to Henrietta Lacks' genomic data.

Simultaneously, the establishment of the Henrietta Lacks Foundation in 2011 aimed to empower Lacks' descendants and influence the use of HeLa cells. Among its objectives, the foundation sought to ensure that the Lacks family played a role in decisions regarding the use of HeLa cells in research.

The decade also saw a shift towards acknowledging the rights and agency of the Lacks family concerning the use and commercialisation of HeLa cells, representing a milestone in the ongoing effort to reconcile the scientific community's reliance on HeLa cells with the ethical imperative to respect the contributions and wishes of the donors and their descendants.

Significantly, Johns Hopkins actively began to publicly acknowledge its role in the Henrietta Lacks story. Early in the decade, the institution launched the inaugural Henrietta Lacks Memorial Lecture – a series that continues to this day – to honour Henrietta and the global impact of HeLa cells on medicine and research. After this, in a statement released in 2017, Johns Hopkins denied that it had profited from the cells, noting: "Johns Hopkins never patented HeLa cells, and therefore does not own the rights to the HeLa cell line." The following year, Hopkins announced plans to name a research building in honour of Lacks.

A lawsuit to change history

While Henrietta's name was finally being recognised alongside the HeLa cell line, the issue of profit remained a thorn in the side for the Lacks family. While it was true that ethical standards were very different during the early adoption of the HeLa cell line in research, by the 2020s, well after the origins of HeLa had been revealed, companies continued to commercialise the results – while the family received not a dime.

In 2021, the Lacks' estate set their sights on one biotech in particular, Thermo Fisher. In a federal lawsuit filed against the company on the 70th anniversary of Henrietta's death, attorneys for the Lacks estate accused Thermo Fisher of unjust enrichment, arguing it illegally commercialised Lacks' genetic material and asked the court to order the biotech to "disgorge the full amount of its net profits obtained by commercialising the HeLa cell line to the Estate of Henrietta Lacks."

The legal battle continued for nearly two years, until, in August 2023, news broke that the two parties had reached a groundbreaking settlement agreement. While the terms remain confidential, representatives from both the Lacks family and Thermo Fisher reported that their clients were ultimately pleased with the outcome.

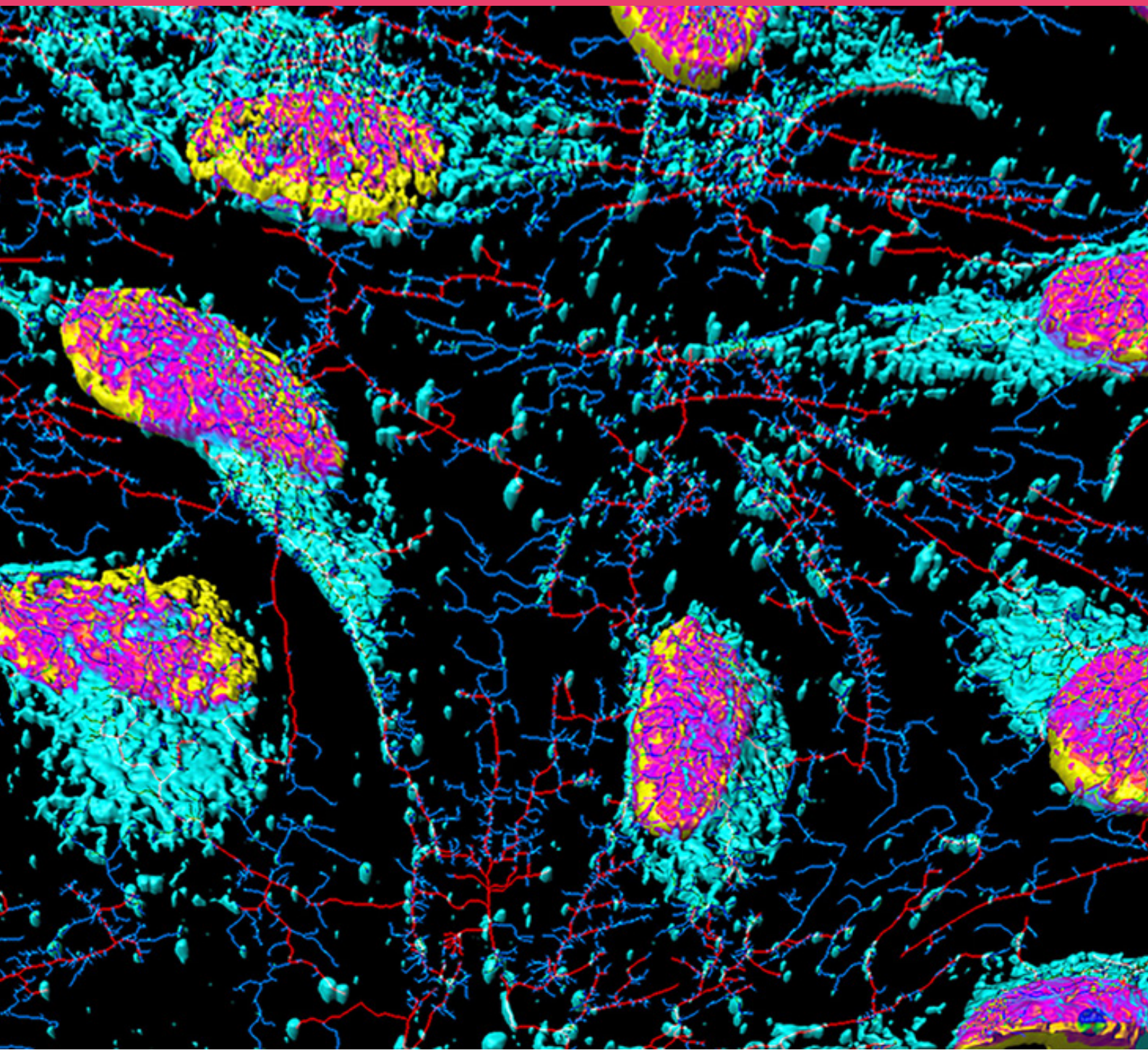
Buoyed by their success, the estate of Henrietta Lacks quickly embarked on another legal journey, this time filing a lawsuit against the biopharmaceutical company Ultragenyx Pharmaceutical. The lawsuit alleges that Novato, California-based Ultragenyx, which develops treatments for rare genetic diseases, uses the famous "HeLa" line of cells "like a dairy farm treats cows" to mass-produce materials for gene therapy. Results of this new legal challenge are still pending.

While the battle over profits continues, Henrietta's overall contribution to the medical world is invaluable. The excitement of court proceedings may dominate headlines, but, behind the scenes, the importance of the HeLa cell line continues to be showcased around the world, helping to drive cancer research that will be used to help treat patients – just like Henrietta herself.

But equally important, though, is the woman who unknowingly provided the world with the power to help millions. For there is no HeLa cell line without her, and you cannot separate the two. The immortal woman, and a legacy of life.

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.



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From participants to partners: The evolution of active patient inclusion in trials

Recruitment numbers are the backbone of clinical research. Without correct recruitment numbers, study results can be invalid, preventing new treatments from becoming available for patients and creating unnecessary additional costs for organisations. Plus, research may not be generalised to practice if the population is not diverse and representative.

However, achieving recruitment targets is just one part of the puzzle; retaining participants poses its own set of challenges.

Here, Professor Melanie Davies – clinical director at the National Institute for Health Research (NIHR) Patient Recruitment Centre, Leicester – sheds light on the evolving role of patients and how engaging with individuals before and during their healthcare pathway can lead to successful recruitment and retention to clinical trials.

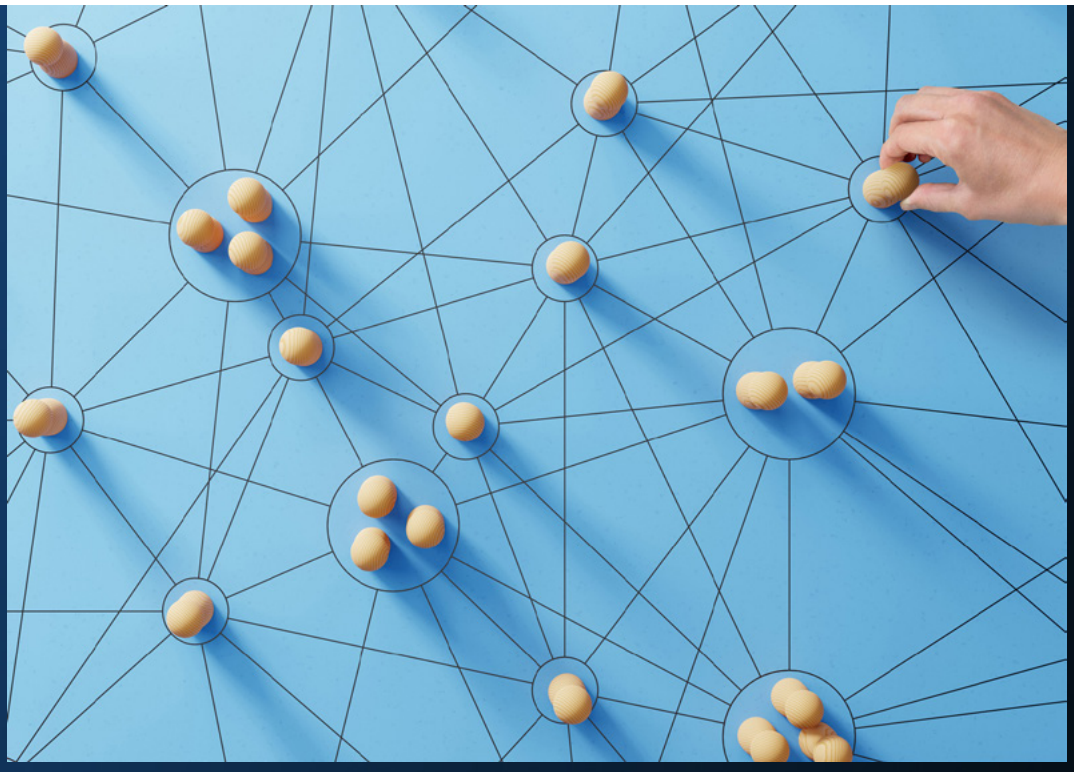
Embed research into the community

At an organisational level, establishing a patient community that is research-aware and research-active is essential. The aim is to develop local communities where hospitals, GPs, and other healthcare-providing sites are viewed as trusted sources for information on research, the benefits of research are known widely around the community, and that people know how to access these systems.

To achieve this goal, community leaders need to be engaged in research. These influential individuals can play a pivotal role, sharing relatable stories that can help to normalise the perception of research in the wider community. In the past, there has been a lack of this kind of research role model, and it is still an area that needs further work.

The power of this community-driven approach was illustrated during the Ensemble 2 COVID vaccine trial. One of our first recruits was a community leader and we were able to promote his involvement in the trial via radio, through interviews, and cascade this via word of mouth to engage hard-to-reach communities. This engagement acted as a catalyst, enabling the recruitment of 700 patients in six weeks.

For research sites, it is important to have links to the community that are not related to a specific study. For example, attending events such as a dance group, where you can go along and talk about research, but you have to get up, join in, and have a dance. In doing so, we are bringing research into an environment that is comfortable for the community, rather than the other way around.



It is becoming increasingly important to work in this way, developing a wide network of different opportunities to engage with a broad range of people to match the varying recruitment needs of different studies.

For example, we have worked closely with the Centre for Ethnic Health Research since its inception to involve and understand the needs of ethnic minority and underserved communities when planning and undertaking research.

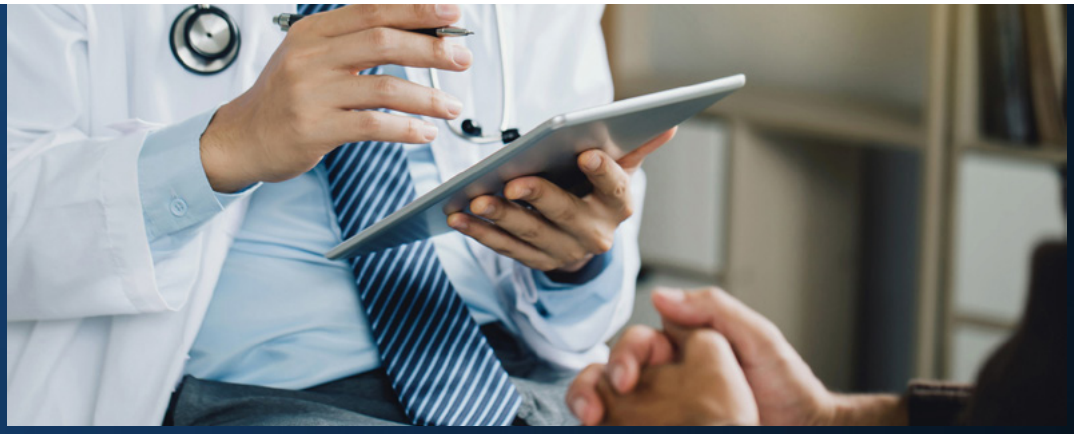
Communication is key

The principles of communication are the same across all aspects of healthcare, being respectful to patients, communicating clearly, and valuing their time. However, these core values can sometimes be unintentionally overlooked.

Researchers can use a variety of methods to engage the patient more effectively, including:

- Translating information sheets into a variety of languages
- Increasing the use of easy to access platforms, such as social media
- Using simple, easy-to-understand language to communicate with potential participants

Building an understanding of engagement considerations among the staff members involved in research can also help. For example, through training, such as the cultural competency training we conduct at PRC: Leicester.



Alongside using a variety of methods to engage patients and participants, it is essential to continue a dialogue with them throughout the trial. One small, but highly impactful, act is simply to thank people for their time taking part in a trial. Participation in a study can last three or four years of their life, so, it is important to always acknowledge that commitment. Moreover, inform them when the dissemination of results will take place in a way that is accessible to many and relay a summary of the results to them via informal methods, such as a coffee morning with the research team.

The use of NIHR Participant in Research Experience Survey (PRES) is another communication tool at our disposal. This allows us to collect feedback from the participants in real time during a study, which we can then put into practice.

Use of technology

The rapid development of technology in recent years has provided more mechanisms for communicating with patients and participants than ever before. Digital pathways can be used to increase participant recruitment by reducing the need for face-to-face appointments.

Social media and websites are a tool that can be easily and quickly updated. Content should be directed towards the participant, ensuring they feel research-ready. For instance, on our website you can find videos such as 'What it's like to be in the PRC?' and 'What it's like to take part in a trial?'.

You can also use data to understand what your organisation needs to improve upon. One way of doing this is by looking across services and analysing information to gain insights. Perhaps you will spot trends suggesting that DNA rates in clinic were higher in some ethnic populations, or related to childcare or language barriers.

Develop relationships with primary care

Primary care sites have a unique connection to local communities, which makes them a promising option for delivering clinical trials.

The datasets in primary care are excellent and there is a trusted relationship with the GP and patient. Researchers can use primary care as an avenue to help identify participants and to conduct the study. In fact, we collaborate closely with primary care providers when delivering commercial trials, often using a Participant Identification Centres (PICs) model. Some studies can be very complex and require specialist delivery, so this model allows sites to refer potential participants to us to conduct the research at our site – thereby reducing the workload for primary care.

Nurture your relationships with primary care providers, even if it is just a study poster in their waiting room. It's another outlet and opportunity to engage patients.

Patient engagement is not one single thing, it requires an organisational approach. Everybody has a role in being an advocate for research. Every patient in the NHS should have access to research, we should not drive worse inequalities by only using the tried and trusted methods in recruitment. Significant investment in this space and a continual improvement methodology needs to be employed as communities, communication, and our understanding change.

About the author

Professor Melanie Davies CBE, MB ChB, MD, FRCP, FRCGP, FMedSci

Melanie Davies is professor of Diabetes Medicine at the University of Leicester and an honorary consultant diabetologist at the University Hospitals of Leicester NHS Trust. She is the co-director of the Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust.

Professor Davies' research interests include the causes, screening, prevention, self-management, and treatment of type 2 diabetes mellitus. She is a National Institute for Health Research Senior Investigator Emeritus and Director of the NIHR Leicester Biomedical Research Centre and co-chair of EASD/ADA's Consensus Report on T2DM Management.

Professor Davies has published over 800 original articles and has over £100m of grant funding. She was awarded the CBE (Commander of the Most Excellent Order of the British Empire) in the 2016 New Year's Honour's List for services to diabetes research.

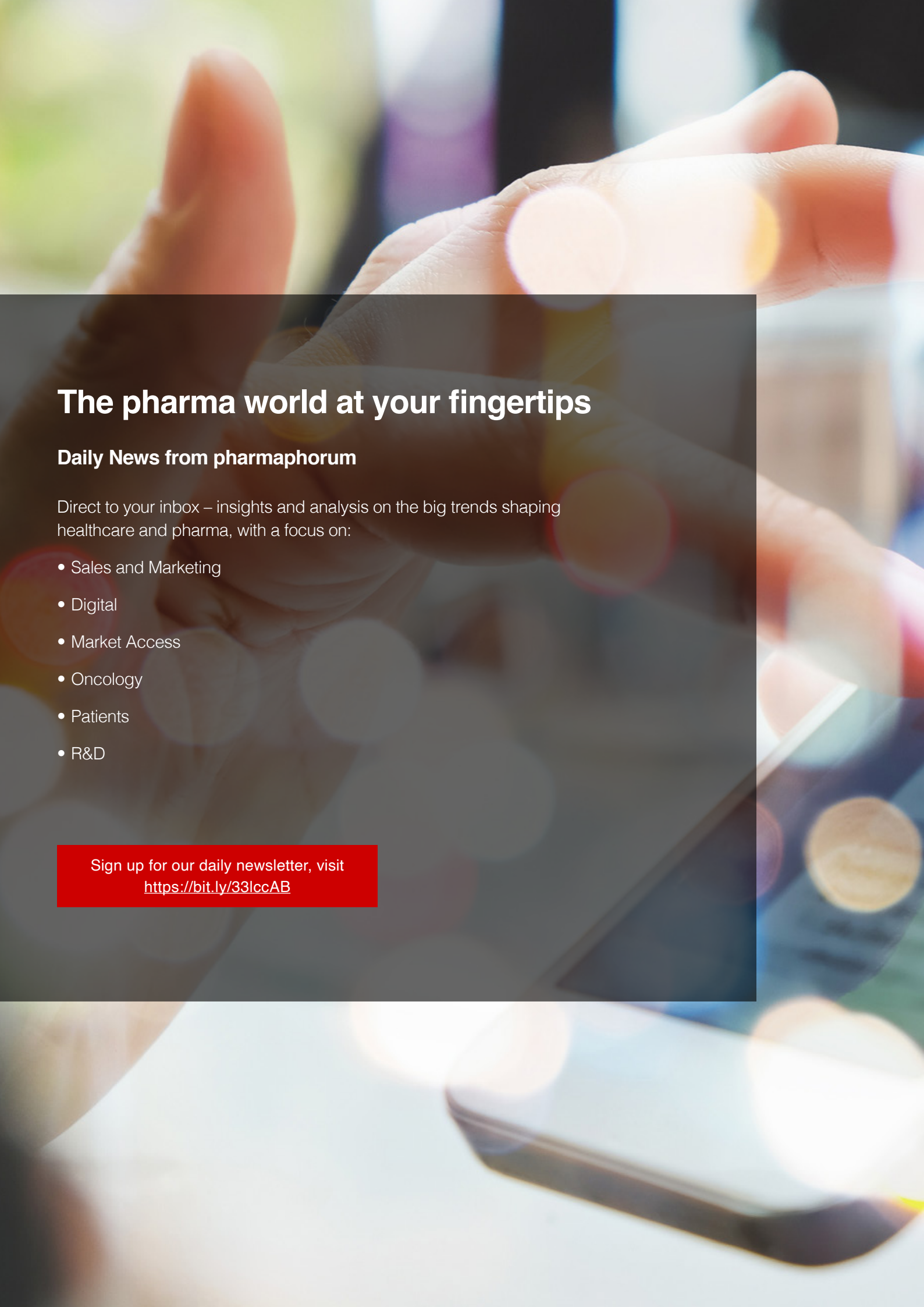
About NIHR

NIHR | National Institute for Health and Care Research

The National Institute for Health Research (NIHR) is the nation's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy

The NIHR was established in 2006 to improve the health and wealth of the nation through research and is funded by the Department of Health and Social Care. In addition to its national role, the NIHR supports applied health research for the direct and primary benefit of people in low- and middle-income countries, using UK aid from the UK Government.



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"Any day now" is today: Pfizer pioneers individual data sharing for US clinical trial participants

At DPHARM 2023 in Boston, Pfizer announced that it has taken the first steps towards sharing clinical trial participants' own data with them – something participants have sought for years.

In healthcare, there are a few problems that everyone from – hospitals to insurers to pharma – can relate to, and one of those problems is data silos. There's a huge amount of data on patients locked away in the vaults of each of those stakeholders, and for reasons that range from business competition to patient protection, it's often not possible to share that data, even when doing so might help patients.

And, ironically, the people with the least access to data are often the patients themselves. After long campaigns, patients are starting to have the right to access clinical notes about them and to download their EHR data, but there's still a lot of data out there that defies the cry of the patient advocate, "Nothing about me without me!"

"Our clinical trial participants have been demanding it of us, and they have been doing it for years,"

This lack of access to one's own data is especially egregious for patients who choose to give their time and energy to participate in a clinical trial, yet might never know something as basic as whether they were in the placebo group, much less have access to the data collected at study visits, which could be useful to their primary and specialty care providers.

"Our clinical trial participants have been demanding it of us, and they have been doing it for years," Pfizer's enterprise clinical trial data sharing lead, David Leventhal, said recently at DPHARM 2023 in Boston. "And it's been a story of 'any day now'."

At the event, Leventhal announced that Pfizer is making individual clinical trial data available to patients in the United States 12 months after their study completion date, starting this past July.

"We have allyship with our clinical trial participants," he said. "How can we reject their demand that they have to access their data, to be able to take that data with them, so that they can have a discussion with their treating physician, so that they can continue their care? That's what they're asking of us. And we have to answer."

Mock up courtesy of Pfizer

A matter of trust

For Pfizer, giving clinical trial data back to patients is not just about convenience but also about their overall relationship with participants.

"Trust is everything when it comes to clinical trials and trust is important to the 100,000 participants who have volunteered for our trials and the 6,000 investigative sites that we work with each and every day," Judy Sewards, head of clinical trial experience at Pfizer, said in another DPHARM presentation. "And so when we start to think about building an experience through trust, it really starts with walking in the shoes of our participants and really listening and learning from their experiences."

Leventhal also sees patient data sharing as part of a larger, important relationship between Pfizer and its participants.

"This is how we build trust, right?" he said. "How is anyone going to want to be a clinical trial participant if there's no trust, if there's no sense that these individuals are looking out for me? Their primary interface is the principal investigator. That person feels like they care about me. But does the sponsor of the study care about me? This is our chance to show that we can, and we do."

"Our participants want to know what happened, how what they did contributed to make a difference; what was learned, how they potentially contributed to a new breakthrough."

The company also recently launched Pfizerlink, a clinical trial registry that makes it easier for participants to find and enrol in a study in the first place. But Seward believes building trust and providing strong patient experience needs to extend through the whole trial journey.

"We make every effort as we begin a trial and end a trial to welcome participants, but also thank those participants who have volunteered because, without them, new medicines and vaccines are not possible. One example that we really are proud of is the commemorative booklet that we brought forward for the tens of thousands of volunteers for our Pfizer clinical trial for COVID vaccine. Much like the polio pioneers back in the day who received a pin for a token of their appreciation and a remembrance of that, we put together something quite similar," she shared.

But a token of gratitude can seem an empty gesture if a company isn't also willing to share what it has learned from a trial with the patients who helped them learn it.

"Our participants want to know what happened, how what they did contributed to make a difference; what was learned, how they potentially contributed to a new breakthrough." Sewards said.

So, this new offering brings the process and the relationship full circle.

"Ultimately, what we want our trial participants to feel is acknowledged for their participation, understood as they go through the process, safe, and that we've done everything that we can do to ensure that they are considered and taken care of," Sewards said.

The latest step in a long journey

As Leventhal noted, participants have been asking for their data for a long time. But Pfizer hasn't simply been dragging its feet. The company rolled out its alumni portal in 2015 to establish a way to track and keep in touch with past participants. In 2021, it started making plain language summaries available through that portal, and shortly thereafter moved the summaries out from behind the portal to Pfizer.com, where anyone can access them.

"And we do all of this while preserving their privacy and confidentiality."

"We started this journey ten years ago when we were working around, well, how do we return aggregate results back to participants? Could we return individual data back to participants?" Leventhal said. "We heard about this thing called Blue Button. We played around with that a little bit, and we couldn't do it because we didn't have the right investments made in the organisation. Our clinical systems weren't up to snuff. We didn't have the infrastructure for a participant to be able to securely gain access to their data. And what we've been doing is chipping away and chipping away and chipping away."

It was important to go slowly in order to maintain trial integrity and protect sensitive health data. But now the company is ready to make the leap, Leventhal said.

"We now can write an R script and extract the data from thousands of patients and load them into individual PDF documents and make them available to clinical trial participants in the alumni community," he said. "And we do all of this while preserving their privacy and confidentiality. We never know who they are. It's their participant ID, their site ID, their study ID, and that's how we match their data up and make sure that the right individual is getting the data. We're now returning data for every US participant who's in a Pfizer clinical trial. But this does not mean that we're doing it for the whole world and that's what's coming next."

And a long way still to go

What else is coming next? Well, Leventhal doesn't believe Pfizer should stop at PDFs.

"PDFs are what participants ask for because that would be the easiest for them," he said. "But we understand that there's technology at play and that machine readable formats are requirements to return data in other localities, like in Europe, for example. So we want to return things in the FHIR standard."

In fact, he wants the data to be available in any format a patient might ask for.

"This is a moral and ethical obligation that we believe that we have."

"We want to return things in a comma-separated value formula format for those participants who want to actually put their data in the spreadsheet and track it. There was a patient who wanted to do that. He was an engineer and said, 'I wanted an Excel format, so [I can], you know, track it over time. And graph.' I was like, 'Cool, you got it'. And of course, we want to integrate with all the best tools, right? That means Apple HealthKit and the ResearchKit."

And, finally, this is one area where Pfizer does not want to stand out from the competition. They continue to work with larger organisations, like TransCelerate, the Innovative Medicines Initiative, and the Harvard Multiregional Center for Clinical Trials, to build standards and processes that allow any trial sponsor to make this data available.

"The ultimate goal is that we have to get every sponsor to do this, and we have to do it really, really well. Because, if one of us does a bad job, then we've all done a bad job," he said. "This is a moral and ethical obligation that we believe that we have. But it's not going to be enough until we're all doing it and that every participant knows that this is available to them."

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.

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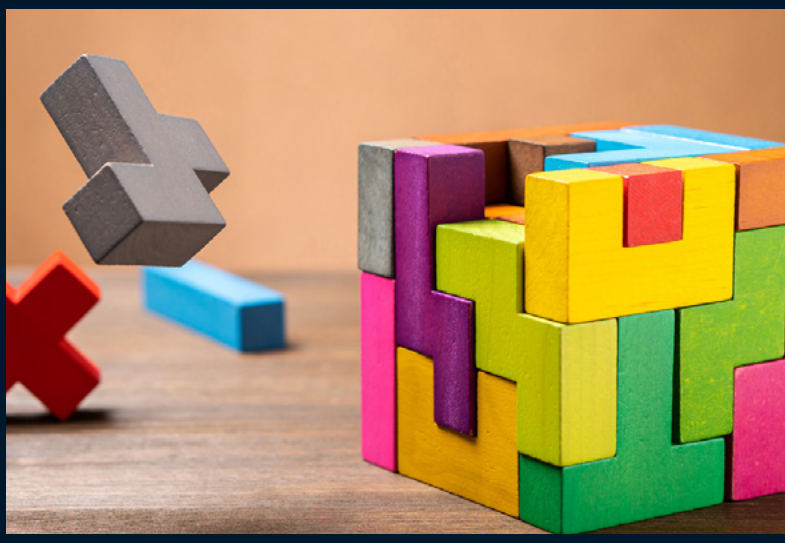
Synchronising experience and data: Combining patient and healthcare provider engagement strategies to optimise business and health outcomes



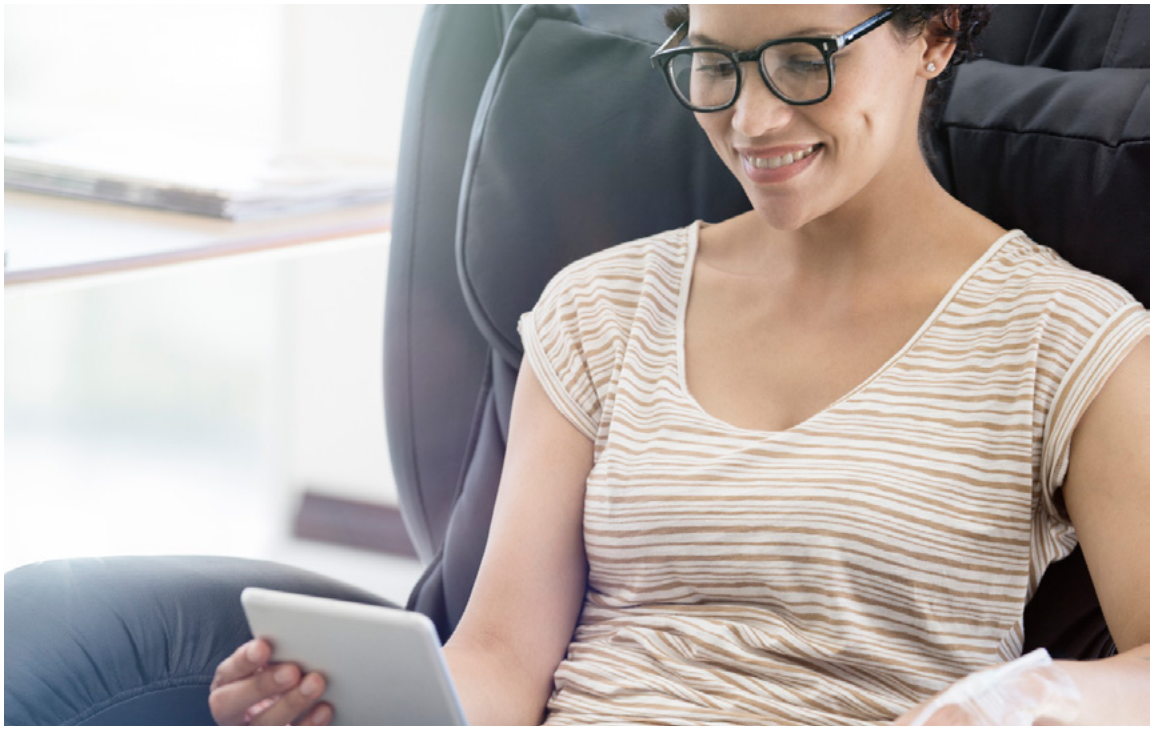
For pharmaceutical companies and other healthcare stakeholders, it is imperative that they understand how patient experience and input needs to be captured, contextualised, and applied to the process of medicine innovation, from research through to provider education and communication, including point of care.

They need to be leading efforts to ensure data and information is made accessible to a lay audience and the end user to promote responsible education and decision-making around the use of their innovation to complement and strengthen their efforts to engage the clinical audience they have more traditionally targeted.

The emphasis on patient-centric medicine development, where the patient and caregiver voice is increasingly included, recognised, and valued in shaping research, clinical trials, and treatment innovation, has been shown to improve both patient and business outcomes. The rise of engaged and empowered patients has the potential to accelerate the development of safer, more personalised, and effective therapies and improve the overall quality of healthcare.

The concept is also marking a significant shift in the provider–patient relationship. An empowered patient actively participates in their healthcare decisions, seeks to gain a deeper understanding of their health and treatment options, and demonstrates a greater investment in the management of their condition and health. By leveraging technology, patients have greater access to information, control over their health data, and the ability to connect with healthcare providers and peers through a diversity of channels. This leads to a more engaged and informed patient population, fostering a culture of patient empowerment in healthcare.

"The traditional passive patient role is shifting, as patients become architects of their experience, armed with knowledge, data, and the motivation to be more active participants in healthcare."



Patient empowerment, as defined by the World Health Organization, is "a process through which people gain greater control over decisions and actions affecting their health." Key to this is the patient's understanding of their role in the management of their health, the need for adequate knowledge enabling engagement with the healthcare provider, and a facilitating environment. Effective patient empowerment is, above all, enablement; patients and caregivers have the right to be informed, motivated, and included, not just at the point of care, but across all research activities and medicine development.

Changing dynamics of decision-making

Healthcare providers are increasingly recognising the importance of involving patients in shared decision-making – tailoring treatment plans to individual preferences and needs, driven in part by an evolution of the consultation model and the increased accessibility of health information and data. An Ipsos Reid survey of over 3,000 clinicians in 2022 described how the dynamics of the decision-making structure are likely to evolve significantly in favour of the patient.

The HCP perspective: the next decade will see significant changes to delivery and decisions related to healthcare

Source: Clinician of the Future Report https://www.ipsos.com/en-uk/clinician-future-2022-report

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The empowered patient should not be viewed as a challenge to the traditional doctor-centric model, but as an opportunity for improved healthcare outcomes. Better-informed patients can have a profound impact on point-of-care decisions in healthcare, based on better-shared decision-making, increased adherence, reduced risk of medication errors and adverse events, better self-advocacy and data sharing, the potential for more efficient resource allocation, earlier intervention when issues arise, and more personalised care.

Incorporating elements of consumer behaviour is key for healthcare stakeholders to understand what drives patient decision-making and to develop strategies to support this.

Other industries, like banking, have responded quickly to address issues of value, convenience, and data interoperability, driven by an acceptance that the consumer experience is critical to adoption of change and innovation. This gives the end user greater control and access to tools and information that support their independence and decision-making abilities.

"Ultimately, a patient will not consume a product they fear, or don't understand, or perceive to hold little value to them."

Understanding the patient experience supports application of clinical data

Understanding the patient experience is crucial for supporting healthcare decision-making for compelling reasons. Clinical studies and data remain the bedrock for determining standards of care and development of robust management strategies. However, to provide care that meets patients' needs and preferences, it's essential to also understand their preferences, values, and expectations.

The opportunity to enhance patient care by understanding their individual experiences and priorities is obvious. So, how much stronger could this approach be if, throughout the medicine development process, treatment options and communications were also informed by collective patient experience? In other words, the more the patient and caregiver experience is built into research, treatment development, and data communication, the greater the chances that the care will support and enhance individual patient decisions and needs.

The process of incorporating patient experience needs to be addressed as a systematic approach and should ensure the involvement of multiple stakeholders, including healthcare providers, to be optimally efficient and effective.

Embedding patient experience into medicine development and point of care has significant benefits:

- **Quality improvement:** Patient feedback and insights into their experiences can highlight areas where research and healthcare services can be improved. By identifying pain points and areas for enhancement, healthcare organisations can make necessary adjustments to enhance the quality of care.
- **Better communication:** Understanding the patient experience helps researchers and healthcare providers communicate more effectively. This includes explaining clinical research and development, scientific data, diagnoses, treatment options, and potential outcomes in ways that patients can access and comprehend.
- **Enhanced engagement:** When patients feel that their experiences and perspectives are valued, they become more engaged in their healthcare. This engagement often results in better compliance with research or treatment regimens and a more proactive approach to managing their health.
- **Reduction of disparities:** By examining the patient experience, healthcare stakeholders can uncover disparities in care delivery and outcomes among different patient groups. This information is critical for addressing health inequities and ensuring that healthcare decisions are equitable and fair.
- **Healthcare policy and regulations:** Patient experiences and feedback often inform healthcare policy and regulatory decisions, influencing access to innovation and care, the broader healthcare system infrastructure, and its governance.
- **Outcome improvement:** Understanding the patient experience helps identify factors that influence outcomes. It can uncover challenges or barriers patients may face in adhering to treatment plans, enabling healthcare stakeholders to work on strategies for better outcomes.
- **Patient safety:** Knowledge of the patient experience can lead to the proactive identification of potential safety issues. Patients often have insights into safety concerns that healthcare providers might not be aware of, which can lead to preventative measures.
- **Efficiency and cost-effectiveness:** Research and healthcare decision-making can benefit from a patient perspective in identifying areas where healthcare services can be streamlined or made more cost-effective without compromising quality.
- **Patient satisfaction and trust:** A positive patient experience is closely tied to patient satisfaction and trust in the healthcare system. Patients who have confidence in their healthcare providers are more likely to follow recommendations and adhere to treatment plans.

"The Pathway tool allows patients to overlay key decision-making moments with the emotions experienced and identify highs/lows over the course of their disease journey.

To support better understanding of the patient experience, Lumanity developed a Patient Pathway tool. Using patient-directed digital tools, the Pathway can unlock insights into the patient journey and decision-making. It is an intuitive, patient-centric digital tool that maps the patient and caregiver lived experiences with a disease or condition over time. A deeper understanding of the lived patient experience helps to better inform engagement plans, commercialisation decisions, and improve health outcomes.

The Pathway tool allows researchers to discover and track when and why patients interact with various types of healthcare professionals. Mapping the patient flow, time to diagnosis, and frequency of visits can determine leverage points and identify opportunities for education and shared decision-making.

Pathway Benefits

Flexible Data Collection

Our platform enables data collection through "considered recall" improving data accuracy versus recall of experience in an interview

Multi-media Integration

Bring the journey to life with video, audio, and written capture. Rich and diverse data formats to enhance the salience and memorability of the patient experience

Prompted and Open-ended

Benefit from prompted content ensuring a consistent level of desired detail and open-ended questions for capturing nuanced responses, resulting in a comprehensive understanding of the journey

Accessible Anywhere

Our web-based platform is readily available on smartphones, tablets, and computers, ensuring seamless access from any device

Put Patients in Control

With a self-directed approach, our user-friendly platform captures vital events and associated details from the patient's perspective, free from any narrator bias

Enhanced Decision-making

View individualized, visual pathways, an intuitive client dashboard, and an advanced analytics package to uncover insights, patterns, and trends for data-driven decision-making

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Developing patient and healthcare provider narratives concurrently makes perfect sense

While better-informed patients can positively impact research and point-of-care decisions, it is essential that healthcare providers are prepared to engage with and support these patients effectively. Developing scientific messaging and engagement for healthcare professionals that considers the patient experience is essential for better education, improving trust and communication, enhancing collaboration, and ultimately achieving better healthcare outcomes. It ensures consistency of messaging and lexicon, relevance of data, and alignment of treatment objectives.

It makes perfect sense, therefore, from a commercial and outcome-driven perspective to consider the patient narrative at the same time that scientific messaging is being developed to support clinical decisions. It is counter-productive, to the point of wastefulness of resources, budget, and strategic opportunity, for companies to be developing patient and healthcare engagement programmes in isolation.

The decision to initiate a treatment and to further persevere and thrive, relies on a series of conversations between the end user and their healthcare provider, in which both partners are starting from an informed position and aligned to common objectives for care.

"Why wouldn't you want your two key stakeholders, the healthcare professional and patient, to understand and apply the same data, information and goals for care?"

Developing an evidence-based patient narrative alongside the development of scientific messaging is not just common sense – it's a strategic imperative. In both cases, the messaging should ideally integrate patient experience and preference data to support clinical datasets.

Synchronising the patient and scientific discourse facilitates a commitment to more personalised, data-driven healthcare to improve the provider–patient dialogue.

Summary: Better together

In our quest for a more patient-centred approach to healthcare, where the patient experience and input are integrated into research, treatment options, and data communication, the goal remains to improve personalisation and healthcare outcomes, enhance the provider–patient dialogue, and foster a culture of patient empowerment.

Fundamentally, in the context of medicine development and healthcare, let us remember that patients are not just recipients of care; they need to be the heartbeat of our programmes, the authors of our innovations, and the purpose that drives our progress.

Behind every clinical trial, every treatment, and every healthcare decision, there is a patient voice and lived experience. We must listen to this, apply it to all stakeholder engagement, and accept it as the currency that will support better personal and business outcomes.

About the author

Susan Daniels – VP, patient strategy and engagement, Lumanity Communications

A licensed pharmacist, Susan has over 25 years' experience in healthcare delivery, the pharmaceutical industry, and medical communications. As VP of patient strategy and engagement for Lumanity Communications, Susan is responsible for the strategic and tactical development of patient-directed programmes to support patient engagement and advocacy in the medicines development initiatives of client partners in the pharmaceutical and biopharmaceutical industry. She is a member of the Lumanity Patient Centre of Excellence and leads the Lumanity Expert Patient Council. She is currently enrolled in a Master's in International Patient Advocacy programme in partnership with the European Patients Forum (EPF). As a blood cancer survivor and advocate, she serves on the Board of Trustees for Lymphoma Action UK.

About Lumanity

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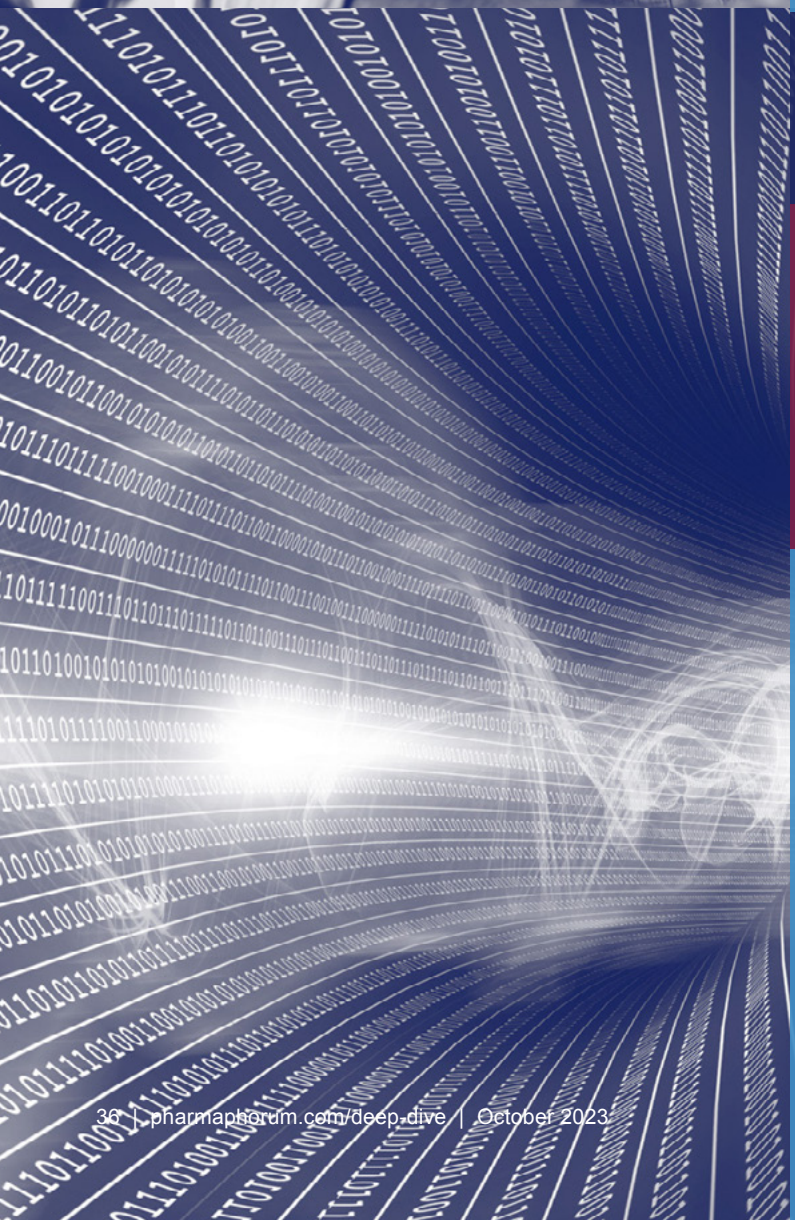
Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimise access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real world insights and evidence that powers successful commercialisation and empowers patients, providers, payers, and regulators to take timely and decisive actionv.

To learn more, contact contact@lumanity.com or visit https://lumanity.com/.

Intellectual property: Striking the balance

For many spin-outs and start-ups in the pharmaceutical space, a key step in getting their science into patients is teaming up with a larger pharmaceutical company.

Such larger companies not only bring valuable financing of the expensive drug development process, but also significant expertise in navigating the challenges that lie along the path to patients. In whichever form they take, these collaborations have risks, so how can both parties protect themselves?



The smaller party

Unsurprisingly, as intellectual property (IP) experts, a key focus of our advice to smaller parties looking for, and negotiating with, larger parties is protecting their IP position.

The first step in this is considering what to disclose and when. Inadvertent non-confidential disclosure will damage the prospect of obtaining patent protection to the company's technology pipeline. However, without some disclosure, how can potential parties be attracted? Thus, the non-confidential package of information released should be designed to illustrate the company's expertise, without significant details.

Before disclosing confidential information to the larger party, a non-disclosure agreement (NDA) – also called a confidential disclosure agreement (CDA) – is essential. This agreement should look to identify the confidential material being disclosed, who at the larger party is entitled to review the confidential material, what the allowed use is, and how long any confidentiality obligation lasts.

Clearly, an obligation to keep the confidential information confidential must also be set out. The sharing of the smaller party's privileged information may then happen in several carefully considered stages. In readiness for more extensive disclosure, perhaps in the context of a full due diligence evaluation, the more detailed considerations in an NDA could include deciding who at the larger party can review the different tranches of confidential information.

Such considerations would need to be discussed with the larger party, as being too restrictive would inhibit their ability to effectively review the collaboration opportunity. In addition, thought needs to be given to what happens if no deal is made, which will typically require the return of the confidential information, and an obligation on the larger party not to use it.

However, a step not always considered requires some foresight. Most collaboration agreements will contain a definition of background intellectual property, that is IP existing before the agreement is signed.

Thus, a smaller company can protect its interests by filing on its own inventions before signing a collaboration agreement. These filings should be made carefully, though, as a poor filing strategy could damage any further inventions made – or fleshed out – during the collaboration.

As an example, many smaller companies will often look to save on fees by filing more than one invention in a single patent application – whilst this can be an appropriate approach when starting out, filing such a 'mixed' application shortly before entering a collaboration might damage the prospects for future patent filings.

Filing a series of initial patent applications covering different aspects of their technology pipeline tends to be a better strategy. This allows for a careful review of the initial filings during their first 12 months (and before they have become public), which should run concurrently with the initial phase of the collaboration. Hopefully, some of the technology in the initial patent application will be in a position to be progressed further, and the relevant initial filings can be supplemented and proceed to a full patent application. Such applications will be published a year and a half after the initial filing.

However, those technologies which have not worked out – or need further development – can have their relevant initial filings withdrawn. For those technologies which are progressing, but more slowly, the initial patent filings can be refiled, resetting the 'patenting clock'. Such a 'withdraw-and-refile' approach would often be much more in line with the approach of a larger party, although a larger party will often simply delay their initial patent filings until their technologies are further advanced.

The larger party

Some of the considerations set out above are, of course, also relevant to the larger party. Typically, pharmaceutical companies will have numerous projects running, some of which may be in a similar area to the work of the smaller party they are looking to partner with. While the larger party is looking to reach a commercially useful partnership, a key emphasis in preparing for discussions with the smaller party is to protect themselves if no agreement is reached or any collaboration fails in due course.

As discussed, the non-disclosure agreement should identify who at the larger party is entitled to review the confidential material. Ideally, this team should be isolated from anyone in the larger company who is working internally on a similar project – by doing so, this should avoid the risk, and any accusation, of the larger company wrongly making use of the confidential information from the smaller company, especially if no subsequent agreement is reached. Further, keeping the confidential information contained within a small group of individuals makes it easier to return to the smaller party without the need for extensive investigations.

The larger party should have less difficulty in identifying its background intellectual property (if any) when entering into any agreement, as it will have comprehensive policies for recording possible inventions, maintaining its trade secrets, and filing patent applications when needed.

A consideration that arises less often is protecting the brand of the larger company. For a spin-out or start-up, a public announcement that they are collaborating with a well-known larger company can bring a reputational boost. However, if the collaboration fails, how will this be handled?

Having a plan in place for public communications after the end of a collaboration is as important as the plan for such announcements at the start of a collaboration. These should include requirements for approval of the proposed text by both parties, agreeing on how the ongoing collaboration is described, and how any termination is communicated. This final step might include requirements for the smaller party to update their website to reflect the end of the agreement.

Final thoughts

As with all commercial agreements, in looking to forge a collaboration between a smaller and a larger company in the pharmaceutical field, planning for the failure of the collaboration is important to protect both parties. However, planning for success is also necessary.

By employing a well-thought-through patent filing strategy before entering into a collaboration, a smaller company can put themselves in a good position, but also lay the groundwork for a more detailed patent filing strategy as the collaboration progresses, and hopefully pave the way for taking the smaller company's science into patients.

About the authors

Robert Watson – Partner, patent attorney, chemistry at Mewburn Ellis
Robert handles patent work in the Mewburn Ellis chemistry team. His work is focused in the pharmaceutical chemistry sector, where he applies his over 25 years' experience in providing commercially focussed strategic advice. His work spans the product and IP lifecycle, including invention capture, drafting, global prosecution, opposition, and freedom-to-operate.

Andrew Williams – Partner, patent attorney, chemistry at Mewburn Ellis
Andrew plays a leading role in Mewburn Ellis's growing 'Speciality Pharma' team. He focuses particularly on supplementary protection certificates (SPCs), patent term extensions (PTEs), regulatory protection, and patent-regulatory listings, as well as commercial and strategic aspects to consider for a medicinal product throughout its development and post-launch phases. This work has involved written and oral proceedings with the European Medicines Agency (EMA) in relation to the EU's Orphan Drug Exclusivity regime.

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'What If?' Poetry as a platform for the patient voice

Patient centricity has been a key focus for pharma in 2023. However, extending beyond the merely discursive topic into sustained and tangible action at scale has been somewhat limited. This year, Sanofi – in conjunction with the release of its 'What If?' report – ran a poetry competition for patients: it asked those going through the healthcare system what they would say if they knew that their voice would be heard, and to share that through poetry.

Held at London's Battersea Arts Centre on 5th October, Sanofi's 'What If?' People's Poem event coincided with National Poetry Day. The campaign is about asking questions and being curious about the self and others, as Sanofi UKIE's country lead, Jessamy Baird, told the audience in her welcoming remarks. What unites us all in our journeys is, after all, health, but everyone's journey is different and varied. So it is that Sanofi wanted to hear from that wide spectrum of patients, their families, and carers.

Serving diverse communities, serving humanity

Image credit: Edwardx, CC BY-SA 3.0 <https://creativecommons.org/licenses/by-sa/3.0>, via Wikimedia Commons

The Battersea Arts Centre (BAC) was an inspirational choice of venue for this linguistic endeavour. Amy Vaughan, executive director and deputy CEO of BAC, explained how it represents inclusivity and accessibility for people, ensuring a sense of community, all of which Sanofi itself strives to serve.

Indeed, wandering through the corridors of BAC, it soon becomes clear that it is a place that brings people from far and wide together – incredibly appropriate for the 'What If?' campaign.

During the pandemic, culture had been shut away for many people, and it was the Arts – poetry and painting and a multitude of avenues of creativity – that brought a sense of relief to many when they felt fear or isolation. There is a power in art that goes to the very core of people.

So, while you might very well ask, 'Why poetry?', in short, it is because of the humanity of the art form. As Baird explained, a scientist or organisation reads words on a page and sees a condition. A poem, by contrast, is evocative: it evokes the true experience of the human patient, and brings that person to the fore.

A spoken word artist and the benefits of actively listening

In total, Sanofi received 149 entries, and they tasked the difficult job of going through them all to their elected 'People's Poet', Jaspreet Kaur, a spoken word artist from East London focussed on gender issues, historical topics, taboo subjects, and positive social change in both the Asian community and wider society.

Invited to the stage by Clara Bentham, Sanofi UKIE's head of corporate affairs, Kaur – previously a secondary school history and sociology teacher – has suffered her own mental health issues and has been in the position of 'patient' as a birthing mother. Channelling her own experiences and harnessing the spirit of the 149 poems, she was asked by Sanofi to create a new poem that referenced them all, spilling the 'chaos and confusion held inside' onto the page, and voicing that to be heard in performance.

But, that necessary platform briefly set aside, how can healthy people benefit from poetry? In 2018, Kaur was involved with the Arts and Wellbeing Foundation, looking at how creative art forms can impact mental health. Within six weeks of one of its workshops running, every single participant had significantly decreased the symptoms of either their anxiety or depression: the potential benefit to mental health services, the costs that could be saved, are clear, she said.

Collective community responsibility and the issue of trust

Most of the entrants to Sanofi's 'What If?' poetry call had never before written a poem. Common themes to submissions included community – especially the collective community responsibility to care for one another, whether in homes, families, or locally – and that more cultural sensitivity is needed in health services, as well as the rather large issue of trust in the healthcare system at all.

This latter point, in particular, Sanofi has been working on both in the UK and globally. The 'What If?' campaign aims to give people a voice, as well as a sense of curiosity and the power to ask questions – and be heard.

And what was literally heard during the evening were four standout poems, with introductory remarks from their writers, as well as Kaur's thematic collation piece.

Patient poesy: Self-knowledge and empowerment

Debra Dulake read aloud 'All About Me', centred on a patient form devised in hospitals in Nottingham to make sure patients don't have to keep repeating themselves. Asking, "What if my health was all about me?", Dulake's refrain – "I know about me" – provided poignant structure to verse seeking "the care and compassion that seems to be going out of fashion".

On Dulake's poem, Bentham later commented: "It was about something so unbelievably simple, yet so blatantly obvious. We depersonalise people, don't we, in the healthcare system? What she was saying at its essence is 'I am a person', and 'care about me' – don't just care about my symptoms and the theoretical, the scientific around my disease area'. Actually think about me as a person, and don't make me have to keep repeating myself and saying things over and over again."

Next, Heather Speake recited from memory 'Monster'. Truly excellent in content and delivery, the performance was made all the more astounding given that, just over four weeks ago, she had had her left kidney removed. The preparation for the Sanofi event, she said, had been perhaps even more nerve-wracking than the operation.

Yet, the poem was, rather, about how, three years ago, she'd had a retinal transient ischemic attack (TIA) – a mini-stroke to the back of her left eye. Added to that, she had entered perimenopause. Everything combined led to her losing her job, and she fell into a dark depression. Speake gained weight and felt, she said, shame and embarrassment, which only exacerbated the problem. What was left was "someone else in the mirror – a monster, right?", and her poem reminded us that "depression comes in many guises, and in many sizes."

Kathryn Anna Marshall's powerful 'If my body were a basket' was delivered by recorded video, as Marshall was unable to journey to London due to her myalgic encephalomyelitis (ME) symptoms. To live with such an illness, she explained, if to live a life of bewilderment and frustration, and she's coped with that for a decade now. However, she can live a measured and reasonably fulfilling life; yet, one losing 130 to 150 days each year to ME. As her poem described, such an existence is to be "like a willow: flexible, extra strong; weeping comes for free".

Tori Pearmain's 'Gold' described her experience with hypothyroidism, IBS, and endometriosis. Based on the Japanese art of kintsugi – where a potter mixes glue and gold paint and puts smashed or broken ceramics back together with golden fracture lines of beauty – there are, she said, a lot of parallels with that craft to living life with an illness. Indeed, Pearmain explained that she sometimes wishes her symptoms were visible, like the gold cracks, as it would make things easier as a patient. Nonetheless, she also added that patient communities have welcomed her with open arms, containing the most empathetic and resilient people she's ever met. After all, for a patient, as the poem reads, "My cracks are me".

Voices of experiential expression:
Wanting to be part of the whole

Also heard during the evening was Bob Stevens, CEO of the MPS Society, a 1982-founded charity focussed on Mucopolysaccharide (MPS), Fabry, and related disorders. Himself a rare disease dad, Stevens explained that a rare disease life can be a lonely life, so their work is to listen to and walk alongside the patient community. Reflecting on Sanofi's 'What If?' campaign, Stevens told of how privileged he felt to see how art, poetry, unlocks the soul, enabling those who have been on a very difficult journey to express themselves in a beautiful way.

The message it sends out, he said, is one of wanting to be part of the whole. In this sense, 'What If?' becomes a call to challenge the way things stand and not accept the world as it is, but to craft it into something better – for all.

And so, to Kaur's 'What If?' People's Poem. Drawing on the entries in their entirety, kintsugi began its discourse, focussing on the cracks, "a new life restored in palms that cared". With queries on love and how never to give up, it asked if there is "a sense of honour in the damage". For, indeed, there is yet "a peace in fragility". At the same time – and poignantly – to live with an illness is often "an abyss filled with what ifs".

Overall, though, Kaur's poem continued that the experience of a patient comes down to survival: "Ashes to ashes and dust to dust, we have to find a sense of trust". Additionally, it must be remembered that these people's destinies are "not diminished by a doctor's diagnosis". And, as the evening made clear, "healing [is] a collective responsibility".

The heart of the matter: Listening to the patient voice

Speaking with Bentham afterwards, Sanofi's head of corporate affairs told pharmaphorum: "All of us who work in the pharmaceutical industry do so because we are purpose-driven and want to help people to live better and healthier lives. It is therefore really important that we take time out on a regular basis, whatever our role, to listen to the patient voice to ensure that the wants, needs, and hopes of patients are truly reflected in the work we do."

"The patient is absolutely at the heart of everything that we do as an organisation," Bentham explained. "Our purpose is to chase the miracles of science in order to improve the lives of patients. At the moment, in the UK, the external environment is very, very challenging, which means that health outcomes are not as good in the UK as they are in other countries, and the inward investment from the life sciences industry isn't as strong. We tried to think, how can we pull together all of these different elements?"

So it was that the concept of 'What If?' was born, focussed on instilling a sense of curiosity to ask the really big questions about how the health and wealth of the nation can be improved.

"We also wanted to really reflect the patient voice, because it's one thing to talk about what governments, healthcare professionals, the NHS, et cetera, can do to come up with solutions to problems," Bentham said, "but how can we engender trust in the healthcare system if we're not actually listening to the people who are using the healthcare system and benefit from the medicines that we produce and develop?"

"That's how we came up with the idea of the People's Poem," she explained. "We really wanted to harness that kind of power of poetry to really listen to people's own very personal experiences."

Sanofi has turned to the Arts before to support the patient voice in being heard: back in February, to mark Rare Disease Day, Sanofi collaborated with rare disease patients and charities to launch This is Rare, a campaign that puts the voices of the rare disease community centre stage, calling for greater recognition, awareness, and advocacy for the 1 in 17 people affected by rare disease in the UK.

"There's something really powerful about all of the creative arts," Bentham concluded. "[They] just get to that raw emotion. I think it opens people up to feelings that they maybe are suppressing or perhaps aren't able to articulate in any other way and certainly aren't able to articulate when they either go to a healthcare professional or talk to people from the pharmaceutical industry. There's always a little bit of a barrier."

So it is that Sanofi has asked 'What If' those barriers can be broken down, and the people have answered with poetry providing power to their voice. The beating heart of the patient has been laid bare: can you hear it?

About the author

Nicole Raleigh, Web Editor

Nicole Raleigh is pharmaphorum's web editor. Transitioning to the healthcare sector in the last few years, she is an experienced media and communications professional who has worked in print and digital for over 18 years.

Calculus's Liz Klein: Investing in a changing landscape

In the ever-evolving realm of healthcare and pharmaceuticals, the intricate dance between innovation and investment shapes the trajectory of groundbreaking discoveries and patient-centric advancements.

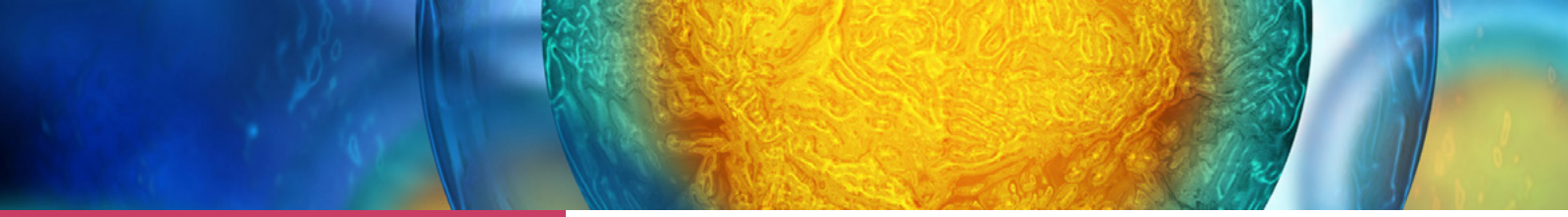
Of course, navigating the complex landscape of financial ventures within the pharma and healthcare sectors requires a keen understanding of trends, challenges, and transformative opportunities. To learn more, Deep Dive editor Eloise McLennan sat down with Calculus Capital's investment director, Liz Klein, to discuss the dynamic world where capital meets compassion.

Eloise McLennan: Can you tell us a little bit about Calculus's work and the investment landscape in the UK?

Liz Klein: Calculus pioneered tax efficient investing through the launch of its first Enterprise Investment Scheme (EIS) Fund in 1999 and, subsequently, its Venture Capital Trust (VCT). In simple terms, we're in the business of helping promising innovative companies in the UK to scale up. These companies often face challenges in raising capital, especially when they are in their early stages and not yet profitable. That's where EIS and VCT come in. The schemes provide a pathway for these higher-risk businesses to access the capital they need, while offering incentives for UK investors to support them.

The government is keen on supporting the growth of such businesses, which is why they offer attractive tax reliefs to EIS and VCT investors. The primary aim of these schemes is to foster the growth of small UK businesses by providing them with access to capital that might otherwise be difficult to obtain, achieved by encouraging people in the UK to invest in them.

In a nutshell, Calculus Capital is all about backing innovative UK businesses across the fastest growing sectors of the economy, and VCT and EIS schemes provide a tax-efficient means for investors to be a part of this exciting journey.



What trends are currently shaping the life sciences industry, and how do you see these trends impacting investment opportunities?

People are living much longer and healthier lives nowadays, and this is becoming the expectation, rather than an exception. We are very much seeing this change reflected in the work underway at firms in the healthcare sector.

There's a ticking demographic time bomb, and it's pushing us to invest in solutions that can help us adapt to this changing landscape. Consider the concept of positive ageing, for instance. It's about finding ways to treat diseases or make it easier to monitor and manage health in an ageing population.

Digital technology remains a strong trend, but this time it's all about supporting diagnostics and healthcare management for everyone. Think about it: how can we streamline healthcare procedures and diagnostics? For instance, imagine managing cancer without having to visit the hospital every few weeks for a scan.

These major trends are converging and, in my view, creating significant opportunities in the healthcare sector. However, there's still a bit of a lag between the exciting technologies we see emerging and the ability to invest in them through public markets. This means that there is a significant opportunity to invest in private companies working in these innovative spaces.

We have seen a growing shift from tech to life sciences when it comes to investment; what is driving this change?

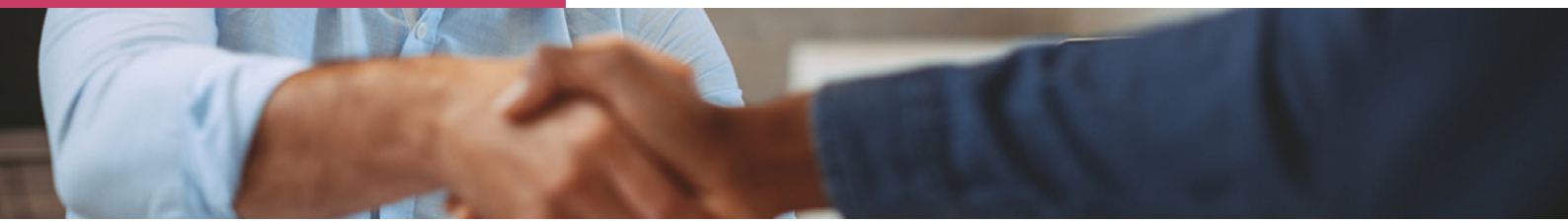
It's interesting; we often witness these cycles of investment, swinging from tech to healthcare and back again. The reason behind this shift lies in the fact that investors who are comfortable with tech also understand the concept of risk. Healthcare investments inherently involve some level of risk, and tech investors are drawn to the idea that healthcare is a long-lasting field with fundamental positives around spending requirements in large populations. It's not solving a problem that will just vanish one day: it's an enduring need.

What particularly appeals to me about this kind of investing is that, while I may not be the one at the lab bench discovering the next cancer cure, I can play a part in helping companies achieve that. As investors, we collaborate with these businesses to make a difference. I believe many tech investors are similarly driven by a sense of responsibility towards improving global health.

What challenges do you anticipate in the life sciences space, and how do you evaluate a company's ability to overcome these challenges?

The challenges are pretty apparent in this field. Statistics show that only around 10% of projects that kick off Phase I clinical trials actually make it to market. However, I prefer not to frame it as 'failure'. Instead, I see it as a matter of safety and efficacy. The things that don't make it through this rigorous process typically fall short of meeting the necessary criteria.

That's why it's valuable to consider investing through funds or venture capital firms. They not only provide portfolio diversification to help mitigate some of that risk, but also bring to the table a wealth of experience and expertise. They can discern what opportunities look like amidst the reality that, yes, some ventures may not succeed.



Can you discuss the importance of strategic partnerships and collaborations in the life sciences sector? What criteria do you use to identify promising partnerships?

There are different ways to look at strategic partnerships. In some cases, we've invested in companies that seek early engagement with major pharmaceutical players. The allure of partnering with big pharma lies in their deep technical expertise, something that even the most seasoned venture capital investors would highly value.

That being said, at Calculus, we have a preference for investing alongside others, especially in healthcare. We believe in the power of diverse perspectives. We want individuals with varying experiences around the table — those who've succeeded and those who've faced setbacks, as the latter can bring valuable lessons to that table. After all, experiencing challenges and obstacles are exceptional learning experiences that can be incredibly valuable for advising businesses.

Given the extended timelines for research and development, how do you balance short-term returns with long-term potential when considering life sciences investments?

Well, it's all about diversification. We make multiple investments, some with the potential for nearer term returns, like those involved in diagnostics or tools and reagents – these tend to have quicker pay-offs than pure biotech plays. At Calculus, our primary focus is on the technology itself. We support businesses through multiple rounds of fundraising and development as they fine-tune their strategies. We embrace this iterative process because we recognise that hitting various technical milestones not only benefits our investors, but also adds value to the businesses we back.

A key aspect is investing in management teams. Having a brilliant idea is one thing, but without the right skills within the team to drive it forwards, success can be elusive. Having an experienced, adaptable management team is fundamental. At Calculus we also work to add additional skills to the Board through our wide network of contacts. A great example of an impressive management team is our latest investment, Laverock. The CEO, David Venables, was previously the CEO of Synpromics, a company we backed through our EIS Fund. We exited Synpromics for an impressive return multiple in 2019.

We have seen a massive boost of interest in AI recently, how do you see such technologies evolving in the sector?

Tech AI, tech bio, and digital health are generating quite a buzz, and it's for a good reason. These buzzworthy terms are likely to revolutionise the way people receive quicker and more efficient treatment.

As these algorithms continue to advance and become more sophisticated, their potential to make a positive impact on healthcare will grow even more substantial. I don't envision a future where clinicians solely rely on algorithms, but as tools to support clinical decision-making, they could prove immensely valuable. In fact, we've observed many businesses we're closely involved with exploring ways to enhance clinician support.

There's also exciting hard-tech innovation in areas like improved surgical training and advancements in surgical procedures themselves. Personally, I'm looking forward to embracing all of these developments, and I believe there are some incredibly enticing opportunities within this space.

Lastly, can you provide examples of lessons learned in life sciences investments, either successes or challenges, and how these experiences are impacting current investment trends?

First and foremost, it's vital to invest in strong management teams. Regardless of how groundbreaking the technology or idea may be, if the management doesn't understand how to bring a product to market, the road ahead can be challenging. Bringing a product to market is the only way that the patient can benefit from the healthcare innovation.

The second lesson revolves around understanding market needs and the associated risks in meeting those needs. It's crucial to have a clear picture of what the market demands and the obstacles that come with it.

Lastly, and perhaps most importantly, don't shy away from embracing truly innovative and game-changing technologies. Over the years, we've seen technologies that were initially met with scepticism, but have since transformed into drugs or therapies that are making a significant impact. Biologics and CAR-T therapies are excellent examples. At the time, they may have seemed almost fantastical, but they've become vital tools in improving people's lives. So, the lesson here is not to fear change, but to wholeheartedly embrace it.

About the interviewee

Elizabeth Klein, investment director, Calculus Capital

Elizabeth joined Calculus Capital in 2022 and has over 20 years' experience in Life Science investing. She joined Calculus from Klein-Edmonds Associates, which she founded in 2015 to support and advise stakeholders in the UK's Life Sciences industry.

Her career spans equity research and investment analysis, and her client base included – amongst others – Radnor Capital Partners, Grant Thornton, and the Bio-Industry Association. She has a BSc in Applied Biology, an MA in History of Medicine, and an MBA. Her role is to source and execute new deals, as well as advising a number of Calculus' portfolio companies.

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.

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Philadelphia, US
Event details

XXIV Brazilian Congress of Clinical Oncology
16-18 November
Rio de Janeiro, Brazil
Event details

9th International Conference on Antimicrobials & Antibiotic Resistance
25-26 November
Vancouver, Canada
Event details

3rd ADC Target Selection Summit
05-07 December
Boston, US
Event details

Middle East/Africa

13th World Congress of The World Society for Pediatric Infectious Diseases
14-17 November
Durban, South Africa
Event details

2nd Global Conference on Pharmaceuticals and Clinical Research
23-24 November
Dubai, UAE
Event details

ASLM 2023
12-15 December
Cape Town, South Africa
Event details

Europe

Frontiers Health
08-10 November
Rome, Italy
Event details

Health Tech Forward
21-22 November
Warsaw, Poland
Event details

Clinical Trials Europe
29-30 November
Barcelona, Spain
Event details

GIANT health
04-05 December
London, UK
Event details

Asia Pacific

CPHI & PMEC India
28-30 November
Delhi, India
Event details

16th World Congress on Toxicology and Applied Pharmacology
06-07 November
Tokyo, Japan
Event details

ASVAC 2023
08-11 November
Cebu, Philippines
Event details

Clinical Trial Supply East Asia 2023
05-06 December
Seoul, South Korea
Event details

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Contacts

Editorial team
Eloise McLennan
editorial@pharmaphorum.com

Sales team
Matthew Brookes
advertising@pharmaphorum.com

Design
Mike Hammerton

A pharmaphorum media publication

www.pharmaphorum.com

pharmaphorum media ltd, Third Floor, Rosemount House, Rosemount Avenue, West Byfleet, Surrey KT14 6LB, UK
Tel: +44 (0)1932 339 264