R&D

Plus: Boosting awareness of rare diseases

Interview with LEO's new R&D lead

Digitalising drug discovery

New models for R&D

pharmaphorum deepdive

February 2021

Deep Dive:
R&D

While we should be hesitant in saying the COVID-19 pandemic will be over soon (I think we were all saying that last spring, after all) there is at least some light at the end of the tunnel, thanks primarily to pharma's historic R&D efforts in new drugs and vaccines.

It seems like a good time, then, for the industry to start doing what it was unable to do at the outset of COVID-19 – planning for the future to ensure the R&D landscape can remain as strong as it is now.

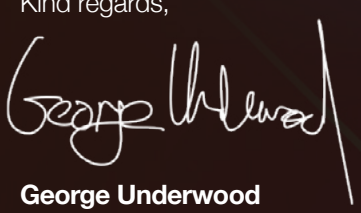
As we find out in this issue, achieving this will require the industry to harness agile working, digitalisation and new, collaborative infrastructures.

Luckily, these are all things that pharma has already embraced during the pandemic, as we see in interviews with LEO Pharma's new R&D lead Jörg Möller and data specialist Dr Maria Chatzou Dunford, as well as experts from the National Institute for Health Research (NIHR), Advanced Clinical and Bruntwood SciTech, among many others.

We also shine a light on some of the smaller life science companies aiding the COVID response, and with commentary from NexGen Healthcare Communications' Emma Sutcliffe look at initiatives and digital innovations that are helping to combat the 'invisibility' of rare disease patients.

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

Kind regards,



George Underwood
Editor, *Deep Dive*

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LEO Pharma's new R&D lead on driving agility in drug development

After 27 years at Bayer, Jörg Möller has moved to LEO Pharma as the company's EVP, global research and development. We spoke to him about the lessons he's taking from his prior jobs into the new role and what it means to be an R&D leader in the modern industry.

As global head of research and development at Bayer, Jörg Möller implemented a strategy that focused on external innovation, increasing efficiencies and reducing costs that could be reinvested into R&D – and these are changes he now wants to bring to dermatology specialists LEO Pharma.

Möller says he was attracted to LEO by the company's aim to take a patient-centric approach to R&D, where every idea is looped back to the question of what it means for patients.

"Innovation is ultimately not defined by us – it's defined by the physicians that prescribe our products, and experienced by the patients who use them," he says.

"It's important to imagine not only how we treat patients today, but also what the standard of care will be 10 years down the road. Then we can consider what these patients really need. What is the disease condition? Is it a debilitating disease? Is it a disease that shortens people's life expectancy? Is it a disease that has a high symptomatic disease burden, but is otherwise more of a nuisance?

"All these questions need to be asked right at the beginning of a new R&D project."

It's an interesting time for anyone to start a new job in pharma, with the COVID-19 pandemic still raging and lockdowns in place worldwide – but leaving aside the pandemic, Möller believes this is also one of the most exciting points in pharma's history.

"Over the last 10-15 years we've seen a vast improvement in our understanding of disease processes and the pathophysiology of biologics, whilst also seeing huge advances in digital technologies. In a way the two cross-fertilise each other, and I believe that over the next 10 years, we will see a revolution in the way R&D is conducted that will allow new and better therapies to reach patients much quicker.

"That will impact the whole value chain. It starts with how we design innovative molecules using artificial intelligence. It continues with the way we run clinical studies using digital capabilities, and how we can use technologies to better identify patients, and find the right treatment for the right person.

"All of this is coming together right now – and in my view, having been in the industry for close to three decades, there's never been a more exciting time to be in pharma."

Focused innovation

Möller believes a company the size of LEO also needs to be focused on specific technology platforms that they believe can really make a difference.

"It wouldn't make sense for us to invest in 30 different platforms, because that would only dilute our efforts," he says, noting digital visual detection technology as an example of an opportunity particularly relevant for skin diseases.

"One of my goals is to work with the R&D and leadership teams at LEO to think about the specific technology platforms that allow us to leverage our existing expertise and competencies, and that we believe will play an important role in the future of the industry, then focus the company on those."

To identify promising new platforms, Möller says he would like to see every employee at LEO also being a scout that always keeps an eye on new developments in their field.

"We also have Science and Innovation Hubs in Boston, Tokyo, and China, with satellites in some of the leading tech hubs around the world, which can pick up on new developments fairly quickly and, ideally, become the partner of choice for innovative companies that are interested in working with pharma."

Pharma's past penchant for siloing has often meant R&D innovations are applied in an ad-hoc way, and in his prior roles and now at LEO, Möller has sought to overcome this by driving home the point that working in the pharmaceutical industry is a team sport.

"It requires lots of discipline and lots of competency to work together, and it doesn't stop at R&D – it needs to involve the whole organisation," he says. "We need to put enterprise thinking at the forefront of our minds and consider what makes the most sense for the organisation as a whole rather than just the function we're working for."

Efficiency in R&D

As with Bayer, Möller says he wants to build more agility and efficiency into R&D at LEO, working with regulators not only to make the experience of participating in a clinical study more welcoming for patients, but also to accelerate the entire process.

In his previous role, part of this involved driving the company to consistently get data from a clinical study within four weeks of the trial concluding – and to go from receiving that data to submitting it within four months.

"Initially, as you might imagine, that goal was met with a lot of resistance, with people saying it couldn't be done," he says. "Of course, it didn't happen overnight – it actually took a number of years – but eventually we were able to achieve it."

And as with his focus on innovation, he says that managing this involved engaging the entire organisation.

"If you want to achieve ambitious goals, you need to take a blank-slate approach, starting from the very beginning of the overall process; not just optimising what you're already doing.

"That's an approach I also intend to bring to LEO."

Of course, COVID-19 has already driven more agile transformation in pharma than anyone could have predicted a year ago.

"There's a joke that's been going around the industry for the past few months: Who has transformed the digitalisation of your company – A) the CEO, B) the CIO, or C) COVID-19? I think all of us would assign it to COVID-19.

"A year ago the entire industry was faced with the situation of patients becoming reluctant to go into hospitals for a clinical trial visit while hospitals had much lower capacity to run trials. It forced everyone to quickly roll out innovative ways of conducting studies."

For LEO this involved innovations like using sensor technology to obtain data from patients 24/7, or shipping study medication directly to patients.

"These are all things we were already working with, but the pandemic has forced us to roll out these technologies much more widely than we would have otherwise dared to.

"That has been a very important learning that has accelerated our understanding of so many technologies."

As Möller points out, this is, in many ways, a glimpse of how R&D will continue to develop from here on out.

"Having discussed this with colleagues across the industry, I can tell you that the feedback from patients has been very positive across the board," he says. "Of course, use of technology will always depend on factors such as the specific indication or drug we are researching, but we can all see that this is a much more efficient way of working that massively reduces the burden on patients."

About the interviewee

Dr Jörg Möller is LEO Pharma's executive vice president, global research & development. In his previous roles he has led the entire R&D value chain from target and drug discovery through clinical development, life-cycle-management and regulatory approvals in multiple therapeutic areas, including dermatology and immunology and a variety of technology platforms like biologics and cell & gene therapies. He has joined from Bayer Pharma, where he was EVP head of R&D and a member of the Bayer Pharma Executive Committee.

About the author

George Underwood is the editor for pharmaphorum's Deep Dive digital magazine. He has been reporting on the pharma industry for seven years and has worked at a number of leading publications in the UK.

Solving the "information challenge" of rare disease diagnosis

Getting a diagnosis is often the biggest challenge facing a rare disease patient in the UK. We take a look at efforts from charities, the government and digital innovators to boost awareness of rare conditions among GPs and make the clinical pathway smoother for patients.

There are more than 150,000 people living with a rare neurological condition in the UK, which taken together means that these conditions aren't actually that rare at all – and that's just for one slice of the wider rare disease population.

This figure comes from a new report by the Neurological Alliance, which is calling for better treatment and care for these 150,000 people.

The report, 'Out of the Shadows: what needs to change for people with rare neurological conditions', includes extensive input from member charities of the Alliance, in addition to expert clinicians.

It points out that while the number of people living with rare neurological conditions equals the number who have other conditions, such as some types of cancer, people with rare neurological conditions are "all too often left behind when it comes to accessing the care and treatment they need".

The authors note that it was likely that more than 200,000 people would be waiting for their first neurology specialist appointments by the end of 2020. These patients risk experiencing further delays and gaps in their support due to overstretched services and waiting lists exacerbated by COVID-19.

"Too often, these people experience slower diagnosis compared to more prevalent conditions," notes Georgina Carr, chief executive of the Neurological Alliance. "Sometimes they don't ever get a diagnosis at all."

One case study in the report discusses a father whose progressive supranuclear palsy (PSP) was not fully confirmed until he had passed away.

Four in ten charities surveyed for the report said diagnosis of the people they represent takes, on average, three to five years.

One solution the report presents is the need for greater awareness of rare neurological conditions in primary care, so that people are more quickly referred on for a specialist assessment when they have neurological symptoms – and can benefit more quickly from available treatments and support.

The power of rare disease data

Carr hopes that, first and foremost, the report itself can act as a starting point for raising awareness of these conditions among GPs.

The document provides a list of known rare neurological conditions and information on the prevalence and incidence of each one, as well as patient groups that work in the area.

"We'd also really like to work with people like the Royal College of GPs to develop any additional training materials that might be helpful for their members in terms of identifying suspected neurological conditions," Carr says.

"It's unlikely that GPs are going to come across more than a handful of rare neurological conditions across their career. In addition, there are hundreds of these conditions, and expecting a GP, with everything else that they've got going on, to be able to pick up on the signs relating to each one is unreasonable, especially considering current pressures."

This is where harnessing existing data can be helpful.

"The sector needs to work with primary care networks to identify any data that might exist about prevalence and incidence in their area and implement 'red flag' tools that can easily be integrated into GP systems."

Of course, by their nature, rare conditions often do not produce much patient data – and the data that does exist is often inconsistent.

"There's a lot of variation, for example in how NHS out-patient data is coded at a Trust level," says Carr. "If we can build some consistency around that, we can be more certain about the quality of the data we're getting from things like hospital episodes statistics.

"The GP databases that do exist now certainly don't code effectively for very rare conditions, which means that we have no idea how much we're spending on support for people with rare neurological diseases.

"We need to work together with the NHS, professional bodies and patient groups to identify what exactly we should be measuring. If we're measuring the right things, we can fund services that are far more responsive."

Carr adds that the enhanced data sharing arrangements that have come out of the UK's COVID response are a great foundation to build upon once the pandemic is over.

Putting the haystack before the needle

It's for these reasons that Rudy Benfredj, co-founder and CEO of Mendelian, frames the identification of rare disease patients as primarily an "information challenge" that is a "systemic issue" within healthcare.

"Healthcare systems have not been designed in a way that allows rare diseases to be found easily," he says. "There are so many silos, and rare diseases often don't easily fit within one particular specialty.

"Ideally, generalist GPs are supposed to funnel these patients to specialists, but it's very difficult for them to get the right information in the right place and at the right time in order to do that."

Like Carr, Benfredj notes that the right knowledge does exist – many rare diseases have expert clinicians associated with them, after all – it's just that the information is not evenly distributed nor easily accessible to most doctors.

"The challenge is to democratise that knowledge at the GP level. You need to have the haystack to find the needle."

It was these thoughts that led Benfredj and co-founders Fran Garcia and Dr Ignacio Hernandez Medrano to build their own 'red flag' tool for rare disease diagnosis, MendelScan – which aims to take a population health approach to the problem.

The company has partnered with the NHS to access medical records at scale.

The technology will use existing diagnostic criteria for rare diseases to filter these datasets, joining the dots that might indicate a person has a rare disease, then flagging to GPs the patients that warrant further investigation – as well as explaining what the clinical guidelines for the disease may be.

The tool is currently in the evaluation phase, where Mendelian will work on refining the criteria for flagging a potential rare disease patient.

"In practice, it will be comparing the signs and symptoms in the patient's medical record with guidelines and information sources that have already been curated by experts," says Benfredj.

Dr Myles Furnace, a former NHS physician and now global digital health partnerships lead at Ipsen – which has partnered with Mendelian on MendelScan's implementation – says that the future of addressing rare diseases via digital will involve finding the right kind of integration between technology and clinical practice.

"We can't just bring in technology for the sake of it. We need to understand that there are deep rooted problems in the healthcare systems that are producing many challenges for people with rare diseases. This is where innovators and entrepreneurs can come in."

The key will be to ensure that tools like MendelScan are seamlessly integrated into a GP's day-to-day workflow, he says.

"Providing this information in a transparent, easily-digestible format allows physicians to easily start supporting their patients and then get those outcomes.

"This is where we see a lot of digital health solutions break down. Physicians are quite sceptical beings – we need evidence, we need publications. We need to know that a technology works, and we need to know how it works. Often digital solutions lack explanations and transparency. We've seen that issue crop up a lot with AI tools."

This education piece is particularly important considering that doctors may have never seen a particular rare disease before, says Benfredj.

"It's important to not just throw an alert at a doctor saying 'this patient might have this disease'. There needs to be more to it than that."

Post-diagnosis

Of course, the challenges rare disease patients face do not stop once the disease has been identified.

The Neurological Alliance's report is also calling for better information to be provided to people with rare neurological conditions and/or their families on diagnosis as a matter of course. The organisation's Patient Experience Survey 2019 found that only a third of people (or families) with rare neurological conditions are provided with written information about their condition at the time of diagnosis.

"Regardless of how prevalent your condition is, having something to take home and help you digest such huge news is incredibly important," says Carr. "Especially as that information can help you access services such as patient support groups."

From there, patients have to hope that there is a treatment available for their condition – but while Carr says that awareness of these diseases is often better among the life sciences industry than healthcare systems, pharma companies face many hurdles when attempting to develop treatments for rare neurological conditions – mostly related to market access.

"This market is actually expanding quite a lot," she says. "The treatments that could, in theory, one day be available to people that currently have no options really are very promising.

"The real challenge is that there's no guarantee that all of that research and development will come to fruition because of barriers in the assessment process, so there is inherently more risk than in other fields."

Carr adds, though, that there are some encouraging elements in the NICE Methods Review, particularly in proposals around the evidence threshold required for assessment of orphan drugs.

Likewise, she says that the UK government's Rare Diseases Framework is a great opportunity for the government to be ambitious in its goals of improving the treatment, care and support for thousands of people living with a rare condition across the country.

"What's missing from that at the moment is concrete plans about who's accountable for different aspects of the Framework. In England that's particularly hard because we have a fairly fragmented health system.

"Sorting out an implementation plan, and, to be frank, putting investment behind it is going to be critical to success."

She says there is an opportunity for the industry, patient groups, and the charity sector to work together as a community to put pressure on the government to set out its plans.

"Patient groups and pharma share many goals in terms of ensuring that access to effective treatment and care is as quick and as appropriate as it can be.

"Many patient groups that we work with are operating on a shoestring. If there are ways in which we could come together to articulate, for example, the standards of care that are required, or think critically about gaps in the current workforce for provision of treatment and support, that could be enormously useful."

About the interviewees

Dr Myles Furnace was a physician in the NHS for 4 years before transitioning into the pharmaceutical industry in 2018. Since moving to industry he has worked in commercial, medical and digital roles. He is currently the global digital health partnership lead at Ipsen.

Rudy Benfredj, co-founder and CEO at Mendelian, is a computer scientist who graduated from Imperial College London with a degree in Engineering, during which he worked with the bioengineering faculty and the Logic and Artificial Intelligence department. He then moved to Tel Aviv to work at med tech diagnostics company Healthy.io. In 2015 Rudy was part of a team of technologists and clinical doctors that founded Mendelian.

Georgina Carr is chief executive at the Neurological Alliance. Prior to this, Georgina was with the MS Society for over six years, overseeing their work to improve MS treatment, care and support. Georgina has a close connection to MS, and is passionate about raising the bar of neurological treatment, care and support across the country. Prior to working at the UK MS Society, Georgina worked on EU health policy for the consultancy Burson Marsteller.

About the author

George Underwood is the editor for pharmaphorum's Deep Dive digital magazine. He has been reporting on the pharma industry for seven years and has worked at a number of leading publications in the UK.

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NIHR | National Institute for Health Research

Inside the UK's leading efforts to restart clinical research

A herculean national effort has seen 69% of paused studies due to COVID restarted under the National Institute for Health Research's (NIHR) Restart Framework. Experts from the institute tell us how those numbers can be further boosted, and how lessons learned from the sector-wide collaboration will change UK research forever.

There has been a remarkable research response to COVID-19 in the UK since the earliest days of the pandemic – but early on that was also coupled with a rapid and significant reduction in clinical research activity as massive pressure on the NHS alongside a national lockdown suddenly made many trials unfeasible.

But even though, at the time of writing, many restrictions on normal life remain in place, the UK research space has seen an impressive bounce back over the last year – with the latest data from the NIHR's Clinical Research Network (CRN) showing that 69% of both commercial and non-commercial studies that were paused have restarted, while 1,103 new studies have been added to the CRN portfolio.

This drive is being spearheaded by the NIHR's Restart Framework, which set out guiding principles and preconditions for starting and restarting research during the pandemic.

This includes considerations such as study validity, safety, capacity, and site readiness. At the same time, a balance needs to be struck between restarting paused studies and allowing urgent COVID-19 care and research to continue, meaning that the framework also stresses the importance of prioritisation.

A key objective of the framework was to ensure that regulators, the HRA, the MHRA, patients, the public, and research organisations all worked together to support the restart and ensure coordinated UK-wide working, while restart decisions had to be made in partnership between local sites, sponsors, and Trusts – and according to Professor Stephen Smye, speciality cluster lead at the NIHR CRN, better collaboration will clearly be of vital importance in the future.

Joint working has been hailed by healthcare and life sciences leaders across the world as perhaps the most important element in the industry's response to COVID.

But Smye says that the UK's collaborative culture is second to none, and with NIHR people, facilities and systems representing the most integrated clinical research system in the world, the country is a unique place to deliver clinical research.

This has allowed UK researchers to answer questions of global importance about COVID-19 treatment and management quickly and efficiently.

"I can't think of any other health system in the world that has managed to deliver the number of urgent public health studies the UK has – and through that the UK has achieved several breakthroughs of global significance, such as with dexamethasone, tocilizumab, and sarilumab," Smye says.

"The pandemic has brought us together with partners in a way that allows us to work much faster than we would have imagined before. It has been quite transformational.

"Now we want to make sure that is baked into the system for the future."

Restart in action

One example of how healthcare systems have implemented the Restart Framework comes from Nottingham University Hospitals NHS Trust.

Professor Steve Ryder, clinical director of research and innovation at the Trust, says that they began by setting up a Restart Group to explore which studies it was possible to reopen.

"This featured a quick review against local criteria, including whether the clinical service linked to the study was up and running, if participants could take part safely, and if the clinical team and sponsor were happy for the study to resume."

Ryder says that involving patients and participants in the process was an essential step to building confidence. "We knew that some people were still anxious about returning to a hospital, so we created a survey to find out more about people's attitudes and approaches that we could take to reassure them.

"The changes that we've made to research and our commitment to embracing new ways of working mean that we wouldn't have to pause studies in the same way for similar events in the future."

Restarting recruitment

For an example of how Restart initiatives are changing UK research now, and in the future, we can zoom in on issues in patient recruitment.

Although lockdowns made recruitment difficult in the early days of the pandemic, this area has also seen a strong recovery.

As of the latest Restart update, 60% of previously paused studies have recruited participants, 268 new studies have opened to recruitment and 174 have recruited patients.

And things are looking bright for recruitment post-COVID – not least because there is now much greater public awareness (and a more positive perception) of clinical research in general. Visits to the NIHR's Be Part of Research website, where the public can find out about clinical research and search for studies to participate in, have increased by 216% between February and December 2020.

"Initiatives like the Vaccine Research Registry have also shown the willingness of people to volunteer and the value that can bring, and that will have wider applicability going forward," says Smye.

Smye adds that the NIHR's "strong principle" of taking into account patient concerns in order to boost recruitment has been a key part of the Framework.

For example, the CRN's Participant in Research Experience Survey asked over 11,500 individuals about their experience of taking part in research during the pandemic and found that safety in healthcare settings was a prime concern, with participants wanting clear information about how the sites they visit will be made COVID-safe.

"This information needs to be as specific as possible to the place they are visiting," says Laurie Oliva, national head of public engagement at NIHR CRN. "For instance, we have heard a number of stories where participants have attended sites and have to use a different entrance than they did previously but had received no clear directions."

People still value the same things in the research experience as they do at other times, such as regular updates, adds Oliva.

"We have found in past surveys that a good relationship with the research staff contributes massively to a positive overall experience, so anything that can sustain this engagement is important – and during the pandemic, a positive experience is still associated with regular, clear information from the research team."

Meanwhile, although embracing digital technology and remote engagement has been a huge boon for trials and recruitment, Oliva warns that researchers also have a responsibility to ensure this technology works as well as possible for participants.

"As more studies use remote delivery, we are seeing many issues with participant use of apps. It is vital that platforms to engage participants in trials are designed to be accessible and that when participants struggle to use them, there is help available.

"We have heard many reports of people leaving a trial because they couldn't use the digital tool required."

Lessons for the future

The efficiencies and improvements gained from COVID-19 research and the Restart Framework are now being embedded into the UK system for future research.

"COVID has had a significant impact on patients with other conditions, the care and research on which they depend," says Smye. "There is an enormous appetite to help patients and the entire research system learn from and recover from the pandemic.

"We've seen the success of the Urgent Public Health initiatives. We now know that this is a system that can and will deliver amazing things."

Smye says the NIHR is continuing to work together with the whole research system – citing examples from the pandemic such as the MHRA's Innovative Licensing and Access Pathway as emblematic of the collaborations and innovations the entire industry wants to see more of.

"That's not to say the post-COVID system will look like the Urgent Public Health system, but there are certainly elements of that approach we want to bake into the new system.

"Meanwhile, initiatives that predate the pandemic, such as the NIHR Patient Recruitment Centres, will come to the fore working with the rest of the Clinical Research Network.

"We are working very closely with partners to make sure that vision becomes a reality."

He adds that this again shows the pivotal importance of joint working to the UK ecosystem.

"The UK has a National Health System, but, uniquely, it also has a National Research System.

"That means that all parts of the system can be joined up, and what we've learned in COVID is that when we do join them up – as we did for the Urgent Public Health portfolio – we can deliver research in a globally-leading way.

"If we can embed that into the system for the future, we will see enormous advantages for the industry, the public sector sponsors and, crucially, patients."

About the interviewees

Professor Stephen Smye is a specialty cluster lead for the NIHR Clinical Research Network based at King's College London. He is also professor in the School of Medicine at the University of Leeds. He was research and innovation director at the Leeds Teaching Hospitals from 2004- 2017 and has been involved with the National Institute for Health Research since 2007, in a number of senior leadership roles.

Laurie Oliva is national head of public engagement for the NIHR's Clinical Research Network. Laurie oversees the Network's Participant in Research Experience survey which aims to promote improvements in research design and delivery through routine collection of participant feedback, as well as the Network's digital public services, Be Part of Research and Join Dementia Research. Laurie is product lead for the NHS Vaccine Research Registry, which aims to support rapid recruitment to vaccine trials by enabling potential volunteers to register their interest in taking part in studies.

About NIHR

NIHR | National Institute for Health 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.

About the author

George Underwood is the editor for pharmaphorum's Deep Dive digital magazine. He has been reporting on the pharma industry for seven years and has worked at a number of leading publications in the UK.

Centessa's founder on the new company's unique R&D model

Putting together a quarter-billion dollar pharma company from ten mergers in four months is not for the faint-hearted – but that's what biotech investment guru Francesco de Rubertis has achieved with his latest project Centessa. In an interview with pharmaphorum's news editor Richard Staines, de Rubertis explained how he did it and how the company is taking a unique approach to R&D.

The idea behind Centessa had been in Francesco de Rubertis' mind for many years – but the influx of investment into pharma and biotech during the last year is what has allowed it to become a reality.

It was only in September last year that the co-founder and partner at life sciences investment firm Medicxi decided that the time was right to realise his vision, which he describes as an "asset-focused" model.

At its heart are ten biotech startups that Medicxi has already invested in and run the rule over – but the philosophy runs deeper than that, according to de Rubertis.

Each company was selected because they are based around a single asset, which in de Rubertis' view would be good enough to be a lead drug in the pipeline of any pharma company.

Initially the company, where de Rubertis will serve as chairman, will focus on 15 drugs.

Only four of the drugs are in the clinic, but each biotech will be focused solely on the development of one or two potential medicines.

The final part of the strategy is that each subsidiary is led by biotech entrepreneurs who are focused around the development of their drugs.

Each CEO is passionate about their projects, and are not career scientists who are looking for a 30 year stay at a big pharma running lots of different projects.

It's this combination of elements that de Rubertis thinks will make the company a success after raising $250 million in Series A investment by General Atlantic, with co-leaders Vida Ventures and Janus Henderson Investors heading a list of blue-chip VCs such as Boxer Capital, Franklin Templeton and LifeSci Venture Partners.

The CEO is Saurabh Saha, formerly global head of translational medicine at Bristol-Myers Squibb.

Chief scientific officer is Moncef Slaoui, who was asked to step down from his gig as chief scientific advisor on the US government's Operation Warp Speed when president Biden took charge in January.

Slaoui is also a partner at Medicxi, and has previous experience at GlaxoSmithKline, which famously trialled a similar R&D approach but with limited success.

The Centessa Subsidiaries are comprised of ApcinteX, Capella BioScience, Janpix, LockBody, Morphogen-IX, Orexia Therapeutics, Palladio Biosciences, PearlRiver Bio, Pega-One and Z Factor.

Projects include treatments for haemophilia, idiopathic pulmonary fibrosis, various kinds of cancer, pulmonary arterial hypertension, narcolepsy, kidney disease and the rare disease alpha-1-antitrypsin deficiency (see box at page end).

Putting all the pieces together has been a tough ask for de Rubertis, who spoke to pharmaphorum immediately after one of the company's first board meetings.

Ten mergers in two months

He told us: "Doing one M&A is a big endeavour. Imagine doing ten – it has been pretty intense.

"I had the idea for a few years but I decided to get going in September 2020."

Most mergers involving several biotechs occur because they are failing and come from the need to salvage something from various burnt-out projects.

But in this case each company was thriving and had offers on the table from big pharma companies wanting to add their drugs to their pipelines.

It took all of de Rubertis' powers of persuasion from his many years in biotech investment to get them to buy into his idea – but once they were convinced the project came together quickly.

De Rubertis explained: "These were not failing companies. In that case it is easy to do mergers.

"I had to have a few calls over weekends and nights. I had to explain to them the full power of the Centessa vision.

"I had to spend two months convincing CEOs then two months doing ten M&As alongside fundraising."

But he said once he had the CEOs on board, all the pieces fell into place. "Execution has been easy," he said.

Big pharma R&D woes

De Rubertis, who made his name as an investor at Index Life Sciences before joining Medicxi, said he expects a better success rate than at GlaxoSmithKline because R&D at Centessa will be more focused and led by data rather than a broader corporate strategy.

While GSK abandoned a similar approach to R&D in 2017 when Emma Walmsley took over, de Rubertis thinks that because each subsidiary will make decisions based on results and data produced by their projects, success is much more likely.

GSK's pipeline is still thought of as lacklustre in some quarters and the company has had to bulk it up with acquisitions such as the cancer drugs firm Tesaro to keep things moving, despite a new approach from research chief Hal Barron.

De Rubertis noted the wider issue with R&D at big pharma, which he says is inherently more conservative and less innovative.

While they are good at getting drugs to patients, big pharma companies sometimes struggle at the early part of R&D because of their risk-averse nature and corporate goals, he argues.

He said: "They are fantastic implementation machines, but that same strength is not matched with the first part of the business, which is early stage R&D.

"The bar for a great molecule goes down when top-down determination informs where research goes. Research is not free to go where the data goes.

"Data is important for a company that has one single product. Every decision will be driven by data."

No career scientists

The R&D culture at Centessa will be radically different from big pharma companies because of the entrepreneurial spirit that drives each of them, according to de Rubertis.

He said that one reason that GSK's attempt at a similar model failed to produce results was the mindset of the people running them.

"They were populated with people who were looking at their career plan; they did not see their career linked to a single molecule."

Meanwhile at Centessa each biotech is run by people who are "single purpose scientists" who will likely go back to academia if their drugs don't work in the clinic.

The drugs being developed are all "gold medal" standard according to Centessa and would be strong enough to catalyse development of a biotech without his intervention.

Centessa is also quite UK-centric, with five subsidiaries in the UK, two in the US, and one each in Canada, France and Germany.

Although the most advanced products (see box at page end) are barely in the clinic, de Rubertis said there will be clinical data from many Centessa programmes emerging over the next three years.

Going forward, the idea is to establish Centessa as a pharma player in its own right and grow by acquisition of single asset companies that would otherwise be snapped up in "bolt-on" deals by big pharma rivals.

De Rubertis added: "We are going to grow by acquisition. Company number 11, 12, or 13 will be anywhere where the management board finds a single asset company at clinical and preclinical stage."

For the entrepreneurs running the biotechs, Centessa offers the kind of infrastructure support and advice available from a big pharma, with each CEO getting shares in return for getting on board.

This provides security in case their individual project does not work out.

The subsidiaries on board so far are also sold on the model that allows them to be operationally independent – within reason.

"You drive the car as long as Centessa does not think you are going down the wrong path," said de Rubertis.

"We are going to have a really good pitch for the scientists."

It's this philosophy that de Rubertis says will lead to Centessa becoming an established name in the industry as a stand-alone entity, rather than another abandoned biotech project.

He concluded: "I want Centessa to be a really big pharma company in the future – with good R&D productivity."

Centessa's subsidiaries

ApcinteX

ApcinteX is developing SerpinPC, a specific inhibitor of the anticoagulant protease activated protein C (APC), for the treatment of haemophilia A and haemophilia B, with or without inhibitors.

Capella BioScience

Capella BioScience is developing CBS001, a neutralising therapeutic monoclonal antibody to the inflammatory membrane form of LIGHT (known as TNFSF14), for the treatment of idiopathic pulmonary fibrosis. Capella BioScience is also developing CBS004, a therapeutic monoclonal antibody to blood dendritic cell antigen 2 (BDCA2), for the treatment of lupus erythematosus (systemic and cutaneous) and systemic sclerosis.

Janpix

Janpix is developing a novel class of selective dual-STAT3/5 small molecule monovalent degraders for the treatment of various hematological malignancies, including leukaemias and lymphomas.

LockBody

LockBody is pioneering a platform technology to develop LockBody CD47 (LB1) and LockBody CD3 (LB2) for optimal targeting of solid tumours by the innate immune system.

Morphogen-IX

Morphogen-IX is developing MGX292, a protein-engineered variant of human bone morphogenetic protein-9 (BMP9), for the treatment of pulmonary arterial hypertension.

Orexia Therapeutics

Orexia Therapeutics is developing oral and intranasal orexin receptor agonists using structure-based drug design approaches. These agonists target the treatment of narcolepsy type 1, where they have the potential to directly address the underlying pathology of orexin neuron loss, as well as other neurological disorders characterised by excessive daytime sleepiness.

Palladio Biosciences

Palladio Biosciences is developing lixivaptan, an oral non-peptide, new chemical agent that works by selectively suppressing the activity of the hormone vasopressin at the V2 receptor, as a treatment for autosomal dominant polycystic kidney disease with the goal of slowing the progression of kidney function decline and avoiding the liver safety issues associated with tolvaptan.

PearlRiver Bio

PearlRiver Bio is developing potent and selective oral exon20 insertion mutation inhibitors intended to have minimal activity on wild-type EGFR and optimal pharmacokinetic properties, for the treatment of EGFR exon 20 insertion (with potential to target and treat Her2 exon 20 insertions) non-small cell lung cancer (NSCLC). PearlRiver Bio is also developing oral inhibitors targeting C797S-mutant EGFR and undisclosed next generation EGFR inhibitors for NSCLC.

PegaOne

PegaOne is developing imgatuzumab, a humanised, non-fucosylated, anti-EGFR monoclonal antibody for the treatment of cutaneous squamous cell carcinoma and other solid tumour indications.

Z Factor

Z Factor is developing ZF874, a small molecule chemical chaperone intended to rescue folding of the Z variant of alpha-1-antitrypsin, increasing serum levels of active protein and reducing accumulation in the liver, for the treatment of alpha-1-antitrypsin deficiency.

About the interviewee

Francesco de Rubertis is a co-founder and partner at Medicxi. Prior to Medicxi, Francesco was a partner at Index Ventures for 19 years, having joined the firm in 1997 to launch its life sciences practice. Francesco currently serves on the boards of a number of portfolio companies, including Palladio Biosciences, Rivus Pharmaceuticals, Orexia and Inexia.

About the author

Richard Staines is senior reporter at pharmaphorum. He has been a journalist since the 1990s and has written for websites, newspapers and magazines. He has always had an interest in health, and has been focusing on the pharma industry since 2010, interviewing industry leaders and covering stories on topics including regulation, mergers and acquisitions, and the latest clinical developments.

Focus on Rare: the invisible burden of rare diseases

Emma Sutcliffe from NexGen Healthcare Communications looks at how patient insights can bring the invisible challenges of living with a rare condition into plain view.

Over the past decade there has been considerable investment by pharma into research for rare disease as the patient voice and advocacy movement have done an outstanding job of raising awareness of the needs of the one in 17 who has a rare condition.

At last, it seems the same level of recognition of the unmet medical need is following through from national and international organisations. In January, for example the UK Government published their policy paper outlining a 'Rare Diseases Framework' which pledges to:

1. Ensure patients get the right diagnosis faster
2. Increase awareness of rare diseases among healthcare professionals
3. Provide better coordination of care
4. Improve access to specialist care, treatments and drugs.

It seems as though we are at the turning point for better provision of care for people living with a rare condition. This is to be commended – especially amidst the ambush of research resources that dealing with the global public health crisis of coronavirus has necessitated. However, what prevails for every patient living with a rare condition is the overriding sense of invisibility and lack of in-depth knowledge about the disease course itself.

This unpredictability causes fear and frustration to patients and researchers alike. To these patients, carers and researchers, there is 'rarely' a day when they have respite from worry about their condition. It is their 'every day'.

For a young adult with cystic fibrosis, something as simple as a friend greeting them affectionately can trigger a fear of infection that might compromise their already vulnerable lungs. The mother caring for a child needing 24/7 ventilation who has to sit in the car in the school car park should her daughter require an urgent tube change is frustrated as to why the doctors at the hospital can't provide more enduring solutions to allow 'normality' as she juggles every aspect of her and her daughter's lives. Dislocating another toe from a simple stumble getting out of the bath isn't life-threatening but is infuriating for someone with Ehlers-Danlos Disease to have to explain to their employer why they will struggle to get to work again. All of these are the everyday impact of life with a rare condition and it will take more than one day, one month or one government publishing a paper to keep making these invisible challenges visible.

Focus on insights

Visibility is key and that's why the zebra has been adopted as a symbol for sharing patient stories about rare conditions. We believe that collaboration with research organisations is also imperative in the diagnosis and development of new medicines to help people living with a rare disease. That's why we dedicate our expert resources under an initiative called 'Focus on rare'.

'Focus on rare' began as a series of insights-gathering sessions with the patient groups we work with to unearth the 'invisible insights' that are the catalyst for pharma to bring everyday solutions and patient support services into focus. It is evolving into a project to transfer insights and expertise between the patient groups we work with and the pharma clients we work for.

In essence, 'Focus on rare' is a social health movement to ensure that physicians and patients have a curated space from which they can quickly and easily understand respectively a) where they can find information to piece together a (more informed) diagnosis or b) gather understanding on their condition. In both cases the goal is directing either physicians or patients to expert physician communities or patient groups and sharing real world experience insights with researchers.

We ask the questions:

- What's the hardest thing about living with/caring for someone with a rare condition?
- How does the condition impact on you every day?
- What would you like the world to know about living with a rare condition?

So far, the responses are overwhelmingly familiar – every day brings fear and frustration (see box).

Fear and frustration: the invisible insight

"Every day with a life-limiting condition is very frustrating and stressful. Even doing simple tasks takes longer and needs more concentration. Because it can affect balance, co-ordination and speech, being accused of being drunk is a common experience."

Alan has ataxia, which is a general term covering a group of rare disorders that cause progressive balance and motor control problems

"The hardest thing is finding healthcare professionals who understand the condition (or even know about it) and can provide tailored care. My body doesn't respond to all treatments the way 'normal' people's do!"

Shona has Ehlers-Danlos Syndrome – a group of rare, inherited conditions that affect connective tissue

"Eve is very rare in her severity of condition: it had been 15 years since they had seen anything even remotely like her at hospital. The condition itself has caused so many other conditions: the unknown is the hardest part."

Becca, mum to Eve who has Congenital Diaphragmatic Hernia, which affects one in 10,000 newborns

"Because it is so rare, there is limited research and medical publications on r(20) so the future for David is unknown – will his condition get any better, stay the same or get worse?"

Alison Watson, co-founder of 'Ring 20', a patient organisation on the search for solutions for her adult son's rare epilepsy

Focus on fatigue and stress

'Focus on rare' has included insights work with people who have ultra-rare, drug-resistant forms of epilepsy, pulmonary arterial hypertension, rare ocular disease, Duchenne muscular dystrophy and rare pain conditions such as vulvodynia and chronic regional pain syndrome. Through this work, we know that the everyday fatigue and fear are the 'common' symptoms of living with rare conditions.

Bee, who has Bechet's Syndrome, a rare chronic auto-inflammatory multisystem disorder of unknown cause told us; "The hardest thing for me is waking up (and getting up) on a weekday morning not knowing if I have enough energy to see me through the working day. Your body aches like you're coming down with the flu – and yet nobody knows you're in pain. Living with a rare condition should be classed as living with a disability – not all disabilities are visible."

A rare disease is defined as a condition that affects fewer than one in 2000 people. However, as Alison Watson explains, having and/or caring for someone with a rare disease affects far more than one in 2000:

"David has to have a support network around him constantly to be able to live a normal life and experience all the things we take for granted. The stress on David and the family is considerable and yet rarely acknowledged."

Transferring insights to focus on research

R&D for rare diseases is challenging – variations in disease subtype, complex pathophysiological backgrounds and clinical profiles, and small patient numbers all make clinical trials difficult. But can more be done for everyday supportive care for patients and family members that makes the everyday challenges more visible? The insights generated from our 'Focus on rare' initiative suggest avenues of commonality for patient engagement, information sharing and community provision – all of which pharma is so excellent in supporting for people with chronic conditions.

Treatments for rare diseases are rare – but patient support and visibility of the challenges that patients with a rare condition face are not. We asked our patient groups for their 'final thoughts' to encourage research organisations.

"There needs to be more funding and opportunity for the basic building blocks for research for rare diseases such as patient registries and natural history studies," says Alison.

This is the priority for medical research. For all participants in our 'Focus on rare' initiative, there was another common wish, articulated by Bee: "Sometimes I don't even have the energy to get up and help my daughter; that makes me sad, just knowing that people might understand the impact of this condition on my everyday life would help me."

Focus on rare means to focus also on basic patient care. Every day.

Thank you to our Patient Participants who kindly shared these insights with us.

About the author

Emma Sutcliffe has been a medical writer and leader in patient engagement since 1995. Emma is head of patient engagement at NexGen Healthcare Communications and a lecturer in patient engagement and social and public health at the University of Cambridge.

About NexGen Healthcare Communications

NexGen Healthcare Communications provides medical communications that create value for clients, healthcare professionals and patients.

Digitalising drug discovery

The oceans of health data out there can be overwhelming for pharma companies to manage – but if extracted correctly, the prospect to develop drugs from scratch in as little as a year is very real, says Lifebit CEO, Dr Maria Chatzou Dunford.

As data and digital technology become vital to every aspect of life sciences, the industry is increasingly looking beyond biologists, chemists, and doctors to drive its drug development – and finding that technology has a chief role to play in the future of medicine.

According to an article by Stephens, Zachary D., et al. on Big data: astronomical or genomical? by 2025 more than 500 million human genomes will be sequenced, creating more data than YouTube and Twitter combined. Mining this data to advance drug discovery and new scientific breakthroughs relies on overcoming the overwhelming conundrum of extracting meaningful insights from massive data that is distributed, non-standardised, complex, and inaccessible to most.

Dr Maria Chatzou Dunford, a bioinformatician by background, recognised the fundamental role technology could play in accelerating drug discovery through overcoming these challenges, and as a result founded AI-bioinformatics technology company Lifebit in 2017.

Lifebit's mission is to revolutionise bioinformatics and biomedical data analysis by bringing together biobanks from across the globe to create an "access portal to the world's clinico-genomic data," Dunford says. The company's Lifebit CloudOS platform enables researchers to query, analyse, and collaborate across large distributed sets of genomic and medical data regardless of where it resides.

The idea to found the company came when Dunford and her co-founder Dr Pablo Prieto Barja were themselves working on analysing genomic and biomedical data for research purposes.

Bioinformaticians by trade, they felt the pain of analysing this data firsthand.

"We found ourselves spending 90% of our time dealing with computational data hassles rather than focusing on the biology and the results," Dunford says. "Gradually we realised this problem was becoming a norm for the entire industry, and that's when we founded Lifebit."

Dunford also believes the industry has just entered a new 'Genomics 2.0' era. Legacy technologies are built for an old genomics model – a world with very few, very small centralised genomic datasets that were not very diverse.

"Today, companies have exponentially more datasets, and genomic data by itself is no longer enough. They need clinical, phenotypic, and observational data to supplement genomic data to uncover next-level insights," says Dunford.

"There's added complexity in that all this data resides across multiple different sites – including research institutions, clinical settings, pharma companies and biotech companies."

The ability to bring all this data together, she says, will completely change drug discovery and give companies an important competitive edge.

"If you look at the history of pharmaceuticals, initially it was all about chemistry, and it took pharma about 100 years to get that right, and it took another 50 years to start getting biology right.

"The next 'big thing' for the new generation of pharma to get right is its approach to data. The industry needs to shift towards operationalising personalised medicine, creating drugs that are more valuable and precise, and unlocking value-based pricing. But they don't have 50 years – to stay competitive they need to innovate over the next five years, and investing in Genomics 2.0 technologies could be a game-changer in bringing new drugs to market in just a few years."

Growing pains with data

Pharma has often failed to keep up with the rapid advances in technology and data. Dunford notes that the amount of data we have today would have been unimaginable even three years ago, and this means that most legacy data platforms that exist within organisations are not built to cope with it.

“There are some innovative pharma companies out there such as Roche and AstraZeneca, but the industry at large is still light years away from harnessing technology to derive data insights to digitalise drug discovery.”

One symptom of this, Chatzou-Dunford says, is companies’ tendency to hire reactively.

Dunford feels the lack of technological advancement in this area is largely due to the fact that historically there have been few data platforms options available, forcing the industry to adopt niche and specialised systems. Consequently, pharma companies hired experts to build in-house systems versus investing in best-of-breed technology.

Accelerating drug discovery

To digitise the drug discovery process, pharmaceutical companies need to better access and manage data, but the industry is far from where it needs to be.

“Companies should aim to get their drug discovery to a point where approximately 80% is digital and only 20% physical, with the latter part just being confirmation,” says Dunford. “Right now it’s the opposite – 80% is physical and observational, and sometimes anecdotal, even. That makes extrapolation difficult, and increases the chance of the trial failing.”

Access to population data speeds the process as the majority of experiments needed to develop some drugs have already been completed in the real world.

“Rather than starting with a random drug in the hope that it will treat a particular disease, you can flip drug discovery on its head and look at which patients are more prone to the disease, understand the genetics and protein-functions behind it, and then work backwards to find a chemical to treat it.”

Consequently, drug discovery timelines could be reduced to as little as one year. COVID-19 vaccines have demonstrated pharma R&D’s ability to move with speed, and Dunford sees no reason why similar timelines can’t be achieved for personalised medicines.

"If you have enough data from hospitals across the world, you essentially have pre-existing clinical trial data that you can analyse endlessly, as well as being able to call in those patients for more samples. It brings the clinical trial into the real world."

Examples of this already exist. Genomics England, for instance, is currently analysing the genetic code of 35,000 patients with COVID-19 to help scientists understand whether a person's genetics may influence their susceptibility to the virus. A paper published in Nature on Genetic mechanisms of critical illness in COVID-19 has already revealed the genes that are linked to COVID-19 susceptibility.

"We wouldn't need to lockdown an entire city or country if we knew more about the genomics of COVID-19," says Dunford. "Instead, we'd only need a specific group of people to stay indoors."

The industry could also start to take a disease-wide approach to drug development by selecting a disease, gathering all the related population and clinical data, bringing together the right tools and experts to analyse and assess potential treatments, and then manufacture the right pill.

"First, though, the entire industry needs to get more data into a state where it can actually be used for better understanding of the underlying disease-genetics, diagnosis, prevention, treatment, and drug discovery."

About the interviewee

Dr Maria Chatzou Dunford is the CEO and co-founder of Lifebit.AI. Maria is a thought-leader and biotech innovator, expert in AI-driven drug discovery, biomedical informatics and federated computing. She is also a passionate entrepreneur and has founded two companies, Innovation Forum Barcelona and Techstars-backed Lifebit. Prior to Lifebit, she was a biomedical researcher, working on developing tools and methods that facilitate the analysis of Big Biomedical Data and promote personalised medicine discoveries. This includes the industry's standard programming framework, Nextflow.

About the author

George Underwood is the editor for pharmaphorum's Deep Dive digital magazine. He has been reporting on the pharma industry for seven years and has worked at a number of leading publications in the UK.

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The landscape for UK R&D SMEs post-COVID

Big pharma might have dominated COVID headlines with its vaccine drive, but behind the scenes an army of SMEs has enabled the UK to respond swiftly to the pandemic. We take a look at how these companies are faring in a difficult environment, and why more recognition from the government, alongside continued investment into new infrastructure, is vital to the sector's future.

The entire UK life sciences industry has stepped up to help the country come out the other side of COVID-19 – helping with everything from diagnostics and vaccines to providing continuity in non-COVID disease areas, even while lockdowns and stretched healthcare resources make 'normal' work near impossible.

Dr Kath Mackay, managing director Bruntwood SciTech, Alderley Park, notes that most of these companies won't be household names, but that small and medium-sized enterprises (SMEs) have been just as important as big pharma to the country's pandemic response.

She highlights companies like **Zenzium**, which has provided AI capabilities for a clinical trial hoping to identify patients at high risk of severe COVID, and Cobra Biologics, which has been part of two consortia helping to rapidly develop vaccines.

In order to support SMEs in the post-COVID world, Bruntwood SciTech is continuing to invest in the infrastructure and development of ecosystems for science and tech businesses across the UK – but the sector's existing challenges in areas like investment and recruitment mean there's still a lot of hard work to do.

The state of SME investment

On the surface, funding for smaller life sciences companies seems to be buoyant. The BIA's recent report, '**The science of success: UK biotech in 2020**', marks the best year for biotech investments ever recorded by the trade association, with UK companies raising a record £2.8 billion in equity finance in 2020.

But Mackay says that while these figures are encouraging, investment can vary greatly on a company-by-company basis, and there have been struggles in the past year around seed and Series A financing.

"It's not been an upward trajectory all year. There is support out there for companies that need it, but we also need to recognise that there are both companies that are thriving and companies that are struggling at the moment."

An unexpected positive of the pandemic is that it has opened up opportunities for some companies to speak to investors they would never have interacted with were it not for remote working, which has broken down geographic barriers between the north and south.

"There's been increased democratisation of how investment works in the UK now that everyone is used to remote working," Mackay says.

But at the same time, she adds, many companies have found it harder to have investor conversations without face-to-face meetings.

In addition, while private investment numbers have gone up, public grant funding has wavered.

"That funding can be crucial for stimulating early innovation and making companies more attractive to investors," says Mackay. "There may be knock-on effects on company growth from that following the pandemic."

Dr Christopher Bullock, CEO and co-founder of **QV Bioelectronics**, based at Alderley Park, says that while COVID's impact on the company's research operations has been minimal, it has been slightly more challenging from an investment perspective.

"Compared to the impact that the pandemic has had on the economy as a whole, we've been very fortunate. We did have one investment deal that fell through, due to issues with the investment company's cash-flow, but from a day-to-day operational perspective we've fared fairly well."

QV is developing an implantable medical device for the treatment of brain tumours, with the stated target of doubling the life expectancy of patients.

The device uses advanced materials to allow the implant to rapidly conform to the size of the cavity in a patient's brain tissue after resection surgery.

Applying electrical fields at specific frequencies from the device to the surrounding brain tissue can then interfere with cancer cell mitosis and slow tumour growth.

The device is still in the early stages of development, with the company going through a preclinical testing regime to ensure safety and regulatory compliance, before starting first-in-man clinical trials in 2024/25.

"In a lot of ways, we were lucky that the pandemic hit us when it did, because it would have actually been much more difficult if we'd been further along in clinical development," Bullock says. "We've already had some delays to parts of the testing thanks to resource challenges. Some of the consultant neurosurgeons we're working with have become involved in treating COVID patients, which would normally be nowhere near their area of expertise."

Nevertheless, he notes that there are likely to be long-term effects from the pandemic on cancer investment as a whole.

"Investors fall into a lot of different categories. Some simply won't have enough spare capital to invest in anything right now, others will want to focus more on antiviral companies, which is understandable.

"But the sad truth is that people are still getting cancer every day. Moving funding from one area to another does have an impact, and it remains to be seen whether that's going to impact fundraising in the long term.

"After COVID we'll certainly see some sense of normality returning to the field – it's just a question of whether things will ever completely go back to how they were."

Meanwhile, the pandemic means that biomedical charities have been forced to close shops and cease fundraising events, and have been unable to fund biomedical research as much as they used to.

"That's going to have knock-on impacts for the oncology research community as a whole," Bullock says.

And while Bullock says the UK is the "best country in Europe" to launch a biomedical company, he believes there are still some systemic problems in funding deep science ventures.

"Investor appetite and the total investment pool is certainly smaller than in our American or Asian counterparts – and to a certain extent, the investors' focus is very different, with more of an emphasis on fintech and digital technologies.

"Meanwhile, a lot of the more traditional strategic investors are focused on drugs and biologics. At QV, we have excellent investors, but companies like ours do sit in a rather small gap, and that would be the case regardless of COVID."

Mackay hopes that the government will recognise that the sector needs sustained investment to succeed in the future and provide more certainty around funding once the pandemic is over. In the meantime, though, she says that science and technology campuses like those in the Bruntwood SciTech network should aim to give companies as much support as they need in accessing funding.

For Bruntwood SciTech this meant having one on one conversations with every company based at Alderley Park, Manchester Science Park and Citylabs at the outset of the pandemic.

"We have everything from digital health firms to manufacturing companies," says Mackay. "We wanted to find out what their individual challenges were, where they needed support, and what kinds of funding schemes they could be directed to."

'Strategic coherence' for diagnostics

Mackay says she'd also like to see more support for the development of additional infrastructure for the diagnostics industry in a post-COVID world.

"The pandemic has shown us that the diagnostics sector is fragmented and underinvested compared to other parts of industry; it could use some more strategic coherence."

Luckily, Dr Joanne Mason, chief scientific officer at diagnostics company **Yourgene Health**, says that the pandemic has massively boosted awareness of the sector in the UK.

"Now the question is how we make the most of that," she says. "We've built many new partnerships and have found ways to get closer to the customer, and that has the potential to lead to long-term change for healthcare if we can harness it."

Yourgene Health began life as two companies – Premaitha Health and Elucigene Diagnostics – specialising in non-invasive prenatal screening and diagnostic care for genetic disorders including Cystic Fibrosis, but soon grew into a broader diagnostics company thanks to acquisitions in Asia and North America.

This global presence gave Yourgene an unexpected head start in their response to COVID.

"We were following closely what was happening across Asia and had set up our own COVID alert teams in the UK," says Joanne Cross, the company's director of marketing. "We were having high-level COVID meetings weeks before the UK lockdown, and had already planned for people to work from home.

"I must admit, I remember thinking it wasn't really going to happen – but then I went to a conference in Dubai at the beginning of February. Seeing the conference so quiet, with people wearing masks, really made it hit home."

The company eventually implemented a hybrid working model. With its headquarters at Bruntwood SciTech's Citylabs campus in Manchester keeping labs open throughout lockdowns, employees can go in to do lab work if needed, while planning and development work is mostly done from home.

And as the pandemic crisis deepened, Yourgene decided to launch its own COVID diagnostic test mere weeks after the first lockdown began.

"Early on we became involved with manufacturing reagents for other companies' COVID tests because of our existing manufacturing capability," says Mason.

"When the UK supply chains started to creak, the government issued a call for diagnostics companies to help scale up testing – specifically with something that didn't use the existing supply chain.

"We saw a need for workplace and private PCR testing that wasn't really being supported by the NHS."

Pivoting like this was obviously a challenge during lockdown, and meant the company had to ramp up hiring significantly – which Cross says was helped by being located in the heart of Manchester's scientific ecosystem.

"We also had to learn how to prioritise what we do and how we spend our resources so that we're working on the right things at the right time," says Mason.

Cross adds: "We still supply molecular diagnostic products to hospitals and labs; services like cancer screening and antenatal care haven't gone away just because there's a pandemic."

The Manchester health innovation ecosystem has also helped the company continue to build partnerships even with lockdowns in place – and is part of the reason why Mason and Cross believe there is a great foundation for the diagnostics industry to build on post-COVID.

"Often we've started conversations with people about the pandemic that have gone in other directions and led to collaborations completely unrelated to COVID," says Mason. "For instance, we now work much more closely with Manchester University NHS Foundation Trust and Health Innovation Manchester, who are also based in Citylabs 1.0, than we've ever done before."

A new way of working

Mackay agrees that the networking aspect of R&D ecosystems is vital to SMEs' growth both now and in the future – and so maintaining a collaborative and communicative culture has been as important to Bruntwood SciTech as keeping labs and offices open.

"Companies come to campuses like Alderley Park, Citylabs and Manchester Science Park because they want to be part of an ecosystem where they can meet potential collaborators on a daily basis," she says.

"We put in lots of hard work to find different ways to get our customers talking through digital means.

"We've actually found that some of the more relaxed events – such as a weekly virtual coffee where people can hang out without a strict agenda – have been most helpful for helping the peer network continue to gel."

She also hopes the network can aid in access to talent – likely to be another challenge in the post-COVID landscape.

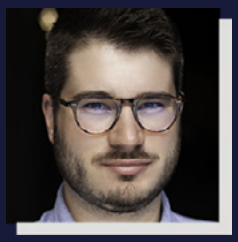
"Many smaller companies do lots of work with younger scientists via internships, but that has become more difficult this past year," says Mackay.

"Some organisations have been offering digital work experience schemes, but I'm not sure they're quite the same in terms of giving lab experience to young scientists and providing a talent platform for businesses."

The future for the sector is bright, and having the right infrastructure will be crucial to further supporting R&D in the years to come.

About the interviewees

Dr Kath Mackay is managing director of Bruntwood SciTech – Alderley Park, home to the UK's largest single-site life science campus and award-winning tech hub, Glasshouse. Her responsibilities include stimulating new business ventures and managing further development of the Park. Mackay joined Alderley Park in 2019 from Innovate UK. In her most recent role there, Mackay was director for ageing society, health and nutrition, and part of the executive management team.



Dr Chris Bullock is the CEO & co-founder of QV Bioelectronics, leading the commercial and technical development of the company. He is a biomedical engineer with expertise in medical device design, biomaterials and bioelectronics and holds a PhD from The University of Manchester, where his research focused on the development of novel graphene bioelectronic devices and the use of electrical stimuli to control cell behaviour. He is passionate about using new technologies to improve patient outcomes.

Dr Joanne Mason is the chief scientific officer at Yourgene Health, leading the development of the next generation molecular diagnostics particularly in the area of reproductive health. Joanne has previously held positions as VP biodiscovery with Cambridge Epigenetix, and director of sequencing and sample acquisition for Genomics England, where she managed the delivery of samples and whole genome sequencing for the 100,000 Genomes Project.

Joanne Cross is director of marketing at Yourgene Health. Joanne has over 18 years' experience in the molecular diagnostics sector as a marketing professional with experience of working in the oncology and reproductive health fields. Prior to joining Yourgene in 2013, Joanne was a freelance marketing consultant working for a variety of biotech and diagnostic companies.

About Bruntwood SciTech

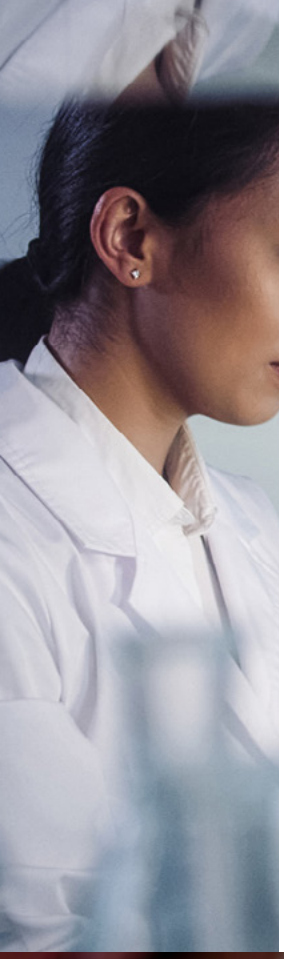
Bruntwood SciTech is the UK's leading developer of innovation districts, creating the environments and ecosystems for science and technology businesses to form, scale and grow.

A 50:50 joint venture between leading property company Bruntwood and Legal & General, Bruntwood SciTech provides high quality office and laboratory space and tailored business support, offering unrivalled access to finance, talent and markets, an extensive clinical, academic and public partner network and a sector-specialist community of over 500 companies.

Bruntwood SciTech has a portfolio of over 1.8m sq ft including Alderley Park in Cheshire, Platform in Leeds, Innovation Birmingham, a cluster in the heart of Manchester's Oxford Road Corridor innovation district, Manchester Science Park, Citylabs 1.0 & 2.0 part of the Manchester University NHS Foundation Trust (MFT) campus and Circle Square – a joint venture with Vita Group and a development pipeline of 850,000 sq ft which includes Birmingham Health Innovation Campus.

About the author

George Underwood is the editor for pharmaphorum's Deep Dive digital magazine. He has been reporting on the pharma industry for seven years and has worked at a number of leading publications in the UK.



From telemedicine to remote site visits: the post-COVID face of pharma research and development

The acute phase of the COVID-19 pandemic not only brought delays, restrictions, and reconfigurations to pharmaceutical research & development in 2020, but also a more flexible response to some long-standing issues with the clinical trials process.

Lockdown rules and safety protocols certainly made it harder for patients to travel to trial sites, while a refocusing of clinical personnel to COVID projects slowed work that wasn't dedicated to the novel coronavirus.

At the same time, pharmaceutical research has very robust structures in place to guide and protect patient safety and those were adhered to, so the impact of the pandemic – at least in R&D – was more at the level of individual circumstances requiring a response.

For Dr Anna Christina Hoerster, director of clinical operations (Europe) at Advanced Clinical, the changes could best be characterised as a series of "very small things, which really did matter" in terms of the bigger picture of a project.

> "The challenge posed by COVID was a trigger for pharmaceutical companies to think outside of the box. We have these very strict rules and models for conducting clinical research, and now the industry was challenged to adapt faster. I believe all these adaptions would have come in the future, but they would have taken longer," she says.

MANAGING COVID'S IMPACT ON R&D

Initially, the pandemic caught much of the sector off-guard. A once-in-a-generation event, few could have anticipated the levels of disruptive change COVID-19 brought and that was certainly true for pharma and healthcare.

Companies scrambled to implement home-working arrangements in place for large numbers of their staff, maintain vital production and supply chains, and support a workforce concerned about their own health and that of their loved ones.

The slow, domino-like format shift of major medical conferences to virtual formats is indicative of just how difficult it was, even for the medical profession, to truly comprehend the implications of COVID.

> "The majority of the pharmaceutical industry were caught off guard by this pandemic," says Dr Ravi Nookala, senior medical writer at Advanced Clinical. "Although they were unprepared for such a global scale of disturbance, they reacted immediately."

The most important consideration within companies' ongoing clinical trials was how to ensure patient safety and then how quickly companies could adapt to ensure that studies continued as planned. "This meant that, while continuing to assess patient safely, companies also had to keep in mind that endpoints were met during a trial and that procedures were adapted on an ongoing basis as guidance shifted and new advice emerged."

"The pharmaceutical industry reacted very well in addressing these things, especially patient safety, by implementing measures where the on-site clinical visit is not necessary," says Nookala, who is PhD-trained and has a strong scientific background.

"They performed remote visits where possible and employed more healthcare providers to ensure patient safety was maintained. That shifted the paradigm a little bit. They also adapted to the demands of COVID-19 protocols, especially the regulatory and safety sides of that as those emerged from the FDA and EMA."

Nevertheless, particularly in the period from April to June 2020, many trials faced disruption, delayed initiation and slower or suspended enrolment. Those trials that went ahead forced pharmaceutical companies to negotiate the impact of local conditions.

> "We had to face the lockdowns and the restrictions on a very project-specific level," says Hoerster. "Looking at this, the implications of the restrictions were very different in different locations. In the US, for example, there were more options for new processes for remote data verification. In the EU, it was more complicated because of the GDPR law, and in addition some site-specific, hospital-specific regulations."

Meeting these challenges required "very unique, very individual solutions and workarounds to see how we can get data and how we can ensure patient safety", Hoerster says.

"Moving forward, I believe there will be a very strong evolution of clinical trials and what can be done remotely."

She's clear that, although not everything can be done remotely, there will be options for clinical trials that will be implemented to be prepared for any such similar situations in the future.

TRIAL SITE VISITS DURING, AND AFTER, THE PANDEMIC

COVID has provided plenty of lessons for pharmaceutical companies as the pandemic stress-tested almost every aspect of their operations.

Within clinical trials one of these lessons is that remote monitoring, though often beneficial, might not reduce the amount of work for site coordinators or other personnel. As Hoerster explains: "We experienced increased time and resource needs for remote monitoring in comparison to face-to-face visits. We thought when these CRAs do not need to travel to the site, we will save time and money, but actually, it was not the case."

Remote monitoring requires a great deal of site time and hours, while for site personnel, for example, if there's a need for in-person sharing of screens during a remote visit then someone must be at the site for the complete duration of the remote visit.

The benefits of overcoming these difficulties and increasing the use of remote site visits – where appropriate – are clear.

> "First of all, the patient burden will be reduced, there will be fewer site visits and it will be less time consuming," says Hoerster. "It will also be easier for the patient to participate and to stay in the study."

She also expects the current resource requirements of remote monitoring to ease off in the future, as new tools and techniques are adapted and developed.

One area of possibility, Nookala suggests, is through the use of online approaches to monitor for adverse events.

"One of the ways that the pharmaceutical industry should think ahead is to have an encrypted application or online portal where a patient can signal an adverse event. If the sponsor is willing to invest in that kind of technology, it could avoid some of these in-person visits."

This would be a way to allow someone from a pharma company's medical function to assess the severity of a potential adverse event and then determine the suitability of a remote visit. This sort of dual approach is likely to be increasingly seen in future projects, and it's likely site qualification visits will focus more on these capabilities in the future.

"The basic takeaway message," Hoerster says, "is that flexibility will increase and this will reduce the patient burden, even if documentation and effort levels stay the same."

Nookala adds: "We have to be innovative. We're in the 21st century and we can find ways to use remote visits and remote monitoring without compromising safety or data security. There are technologies available today, but it's up to the pharmaceutical industry to capitalise on what we experienced last year."

DIGITAL CHANGES TO STUDIES

One of the major changes that impacted healthcare during 2020 was a coming of age for telemedicine as participants did everything they could to avoid in-person visits as awareness increased of digital options for healthcare.

"This should have happened a long time ago," says Nookala, "this move toward digital platforms like telemedicine and utilising the available resources to minimise patients' need to travel, while safeguarding their safety. It should have happened a long time ago, but hindsight is always 20/20."

Nookala, who's passionate about the possibilities of telemedicine, says that if technology can be used in the form of an Apple Watch to take ECG measurements then there will be ways telemedicine can adapt and fit around patients.

"Every single trial is different," he notes, "but wherever possible, if we can do any assessments remotely, using an app or through a healthcare provider, let's go for it. Otherwise, bring them in to the clinic where it's not possible."

The early momentum towards telemedicine appears to be building. In the US, a recommendation by the Centres for Medicare & Medicaid Services (CMS) that was announced at the end of 2020 will see telemedicine offered to patients with more than 60 different acute conditions. Those needing treatment for the likes of asthma, heart failure, pneumonia and chronic obstructive pulmonary disease (COPD) could receive at-home care and monitoring.

Meanwhile, in the UK, the government has said the adoption of telemedicine across the NHS is a vital part of the response to COVID-19. Health secretary Matt Hancock spoke over the summer of the "moment of exposure, of stark clarity" provided by COVID-19. "Coronavirus has tested every single part of our infrastructure, giving us a new appreciation for what works and what doesn't," he said signalling that consultations should, wherever possible, be remote by default.

The same mindset should be applied to the way the pharma sector works in the future, Nookala says. "More and more during the pandemic, the pharmaceutical industry adapted quickly and used telemedicine much more than it normally would have. That would be one of the good things to be retained going forwards, because it worked. Perhaps it was not seamless, but it was tested, and it withstood the test. Going forward, we can make fine tweaks and make it much more seamless and streamlined."

THE FUTURE OF R&D

Divining the future of R&D from its recent past, it's clear that there's always room for further improvements in clinical trials and how they're conducted – and that pharma companies can be far more responsive than they might believe possible.

"Because of the pandemic, innovation is coming to the forefront, and companies are doing this as a matter of urgency," says Nookala, adding that now pharma's mindset needs to be one of "we can adapt, and we will adapt".

Looking to the future shape of pharma R&D, he says companies should look to continue to allow more people to work remotely, make trial endpoints more patient-centric, and be more responsive.

Clearly, flexibility will continue to be required – both on the part of pharma companies and the suppliers they work with. As Hoerster notes: "One of the things that I learned during 2020 was that it was really easy, for us as a mid-sized CRO, to support pharma companies with the changes they had to make because we were able to adapt very quickly to provide more customised or tailored solutions."

She concludes: "The new normal will have to include a massive element of flexibility and risk assessment upfront to be prepared for those kinds of situations. With this flexibility, we might develop new models, which will certainly include more remote monitoring visits and a greater use of telemedicine."

About the interviewees

Dr Anna Christina Hoerster, director, clinical operations (Europe)

Anna is a clinical development professional with more than thirty years of healthcare experience. As a health economist she graduated in theoretical medicine and is a proficient expert in clinical trials of phase I-III including IIT and medical devices with more than 16 years of industry experience in various roles of clinical operations.

Dr Ravi Nookala, senior medical writer, Europe

Ravi is a senior medical writer with over six years of medical writing experience in oncology. He writes clinical study reports, study protocols and various other GCP-compliant documents. Prior to taking up medical writing, he worked as a cancer biologist for 13 years in world-class laboratories at the University of Cambridge, UK.

About Advanced Clinical

Advanced Clinical is a global clinical development organisation that provides CRO, FSP and strategic resourcing solutions for biopharmaceutical and medical device organisations. Our mission is to deliver a better clinical experience. To learn more, visit www.advancedclinical.com.

About the author

Dominic Tyer is a journalist and editor specialising in the pharmaceutical and healthcare industries. He is currently pharmaphorum's interim managing editor and is also creative and editorial director at the company's specialist healthcare content consultancy pharmaphorum connect.

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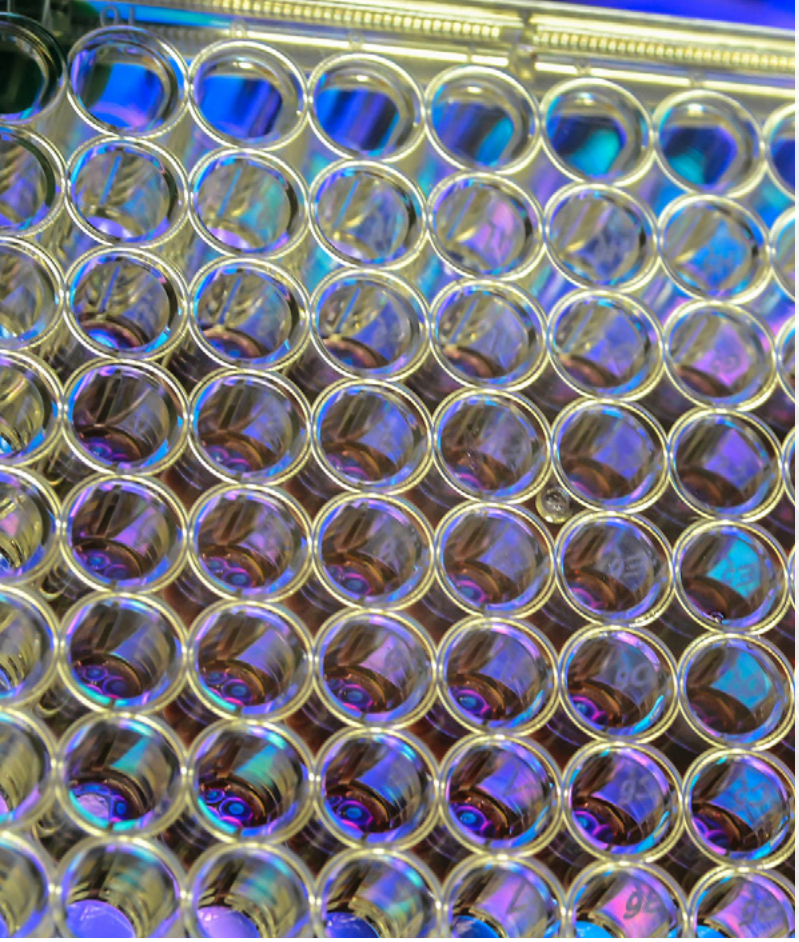


Culture changes – FUJIFILM Irvine Scientific's COO on cell therapy, COVID vaccines and 50 years of the company

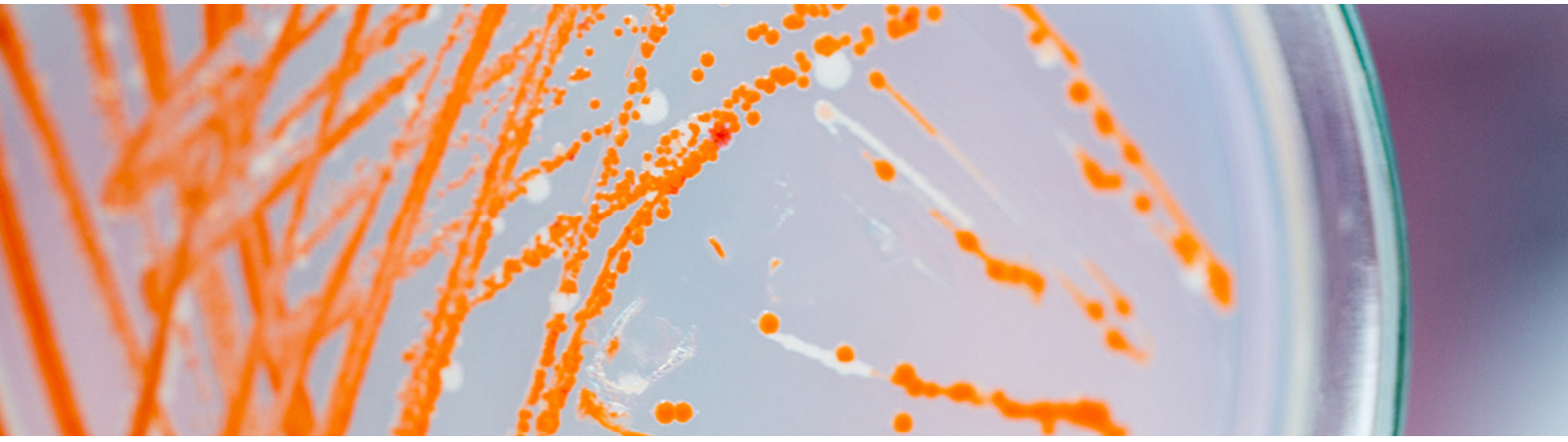
From animal processing, to cell therapy and AI, Tim Mullane, president, and chief operating officer tells pharmaphorum how FUJIFILM Irvine Scientific has evolved to become one of the top manufacturers of cell culture media.

Although Irvine Scientific joined parent company Fujifilm in 2018, its roots can be traced back to the 1970s, where it started life as a bovine and animal serum processing company.

Founded by three people working in the medical diagnostic business, the Japan Energy Company (JEC) acquired a majority stake in the firm in the mid-80s.

Less than a decade later, it acquired a portion of Hana Biologicals, one of the first manufacturers of serum-free media for Chinese Hamster Ovary (CHO) formulations and what is now considered the gold standard for biologics production.

It was this acquisition that paved the way for the company's focus on cell culture, says Tim Mullane. As chief operating officer, Mullane has supported rapid expansion of the business as it branches into new geographies and business areas including the cell therapy market.



"When I joined the company over 10 years ago it was known for its in vitro fertilisation (IVF) business. The company was also moving from being a general supplier for research applications and more into the medical and life sciences business," he says. "We knew that based on what we had developed and acquired there was a great opportunity to serve the biopharma market."

The company invested money to develop innovative media and modernise CHO formulas, so they were more 'purpose-designed', says Mullane. "We call it Rational Media Design, for specific applications. We also began servicing several small to medium-sized biotech's that were being underserved by the larger media companies."

According to Mullane, this strategy was the foundation for the business taking off. "We went from a very small market player to a significant one. We're definitely in the top tier of bioprocessing media suppliers at this point, which is phenomenal growth over the last decade."

'Aggressive' approach to cell therapy

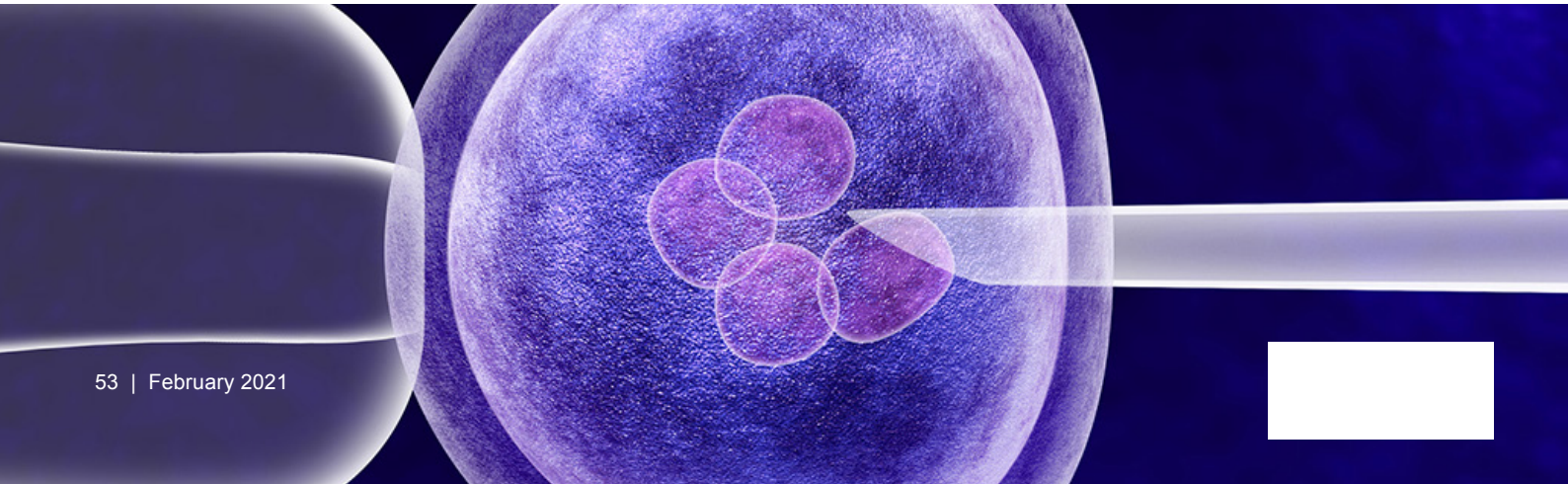
The foundational businesses in embryo culture and bioprocessing also helped the company move into the emerging market of cell therapy in 2013.

"The reason we did this is because the market was already coming to us due to our expertise in embryo culture, and IVF media. These are highly regulated markets so our knowledge and experience in manufacturing high-quality products was very appealing to the cell therapy players."

With freezing of cells and gametes taking place for decades in the IVF market, the company's innovation proved invaluable.

"We were an innovator in moving clinics away from using slow freezing techniques – which does not offer high recovery – to vitrification, which is flash freezing and very high recovery (almost a 100% recovery). We use that to help cell therapy companies be able to freeze their cells as well."

The company has developed a suite of media and targeted the most advanced areas of cell therapies including mesenchymal stem cells, T cells, natural killer cells, and dendritic cells.



"We've launched ourselves in the market in a very aggressive way," says Mullane. "But we are passionate about cell therapy – as is our parent Fujifilm."

However, cell therapy companies are facing challenges in trying to scale up processes in an efficient way. "It's been a real struggle for companies and our role is to help them go through the multiple steps associated with isolating, washing, expanding, and then freezing those cells in preparation for the therapy. We work alongside not only the companies developing those therapies but also the platform technologies they're offering from the equipment, to different portions of the process."

FUJIFILM Irvine Scientific is also marking special milestones, last year celebrating its 50th anniversary and this year preparing to open a new European facility in Tilburg, Netherlands. The facility will reside within one of Fujifilm's largest production centres outside of Japan. The >100,000 square foot space will be used for manufacturing of dry powder media, liquid media, and downstream bioprocessing liquids.

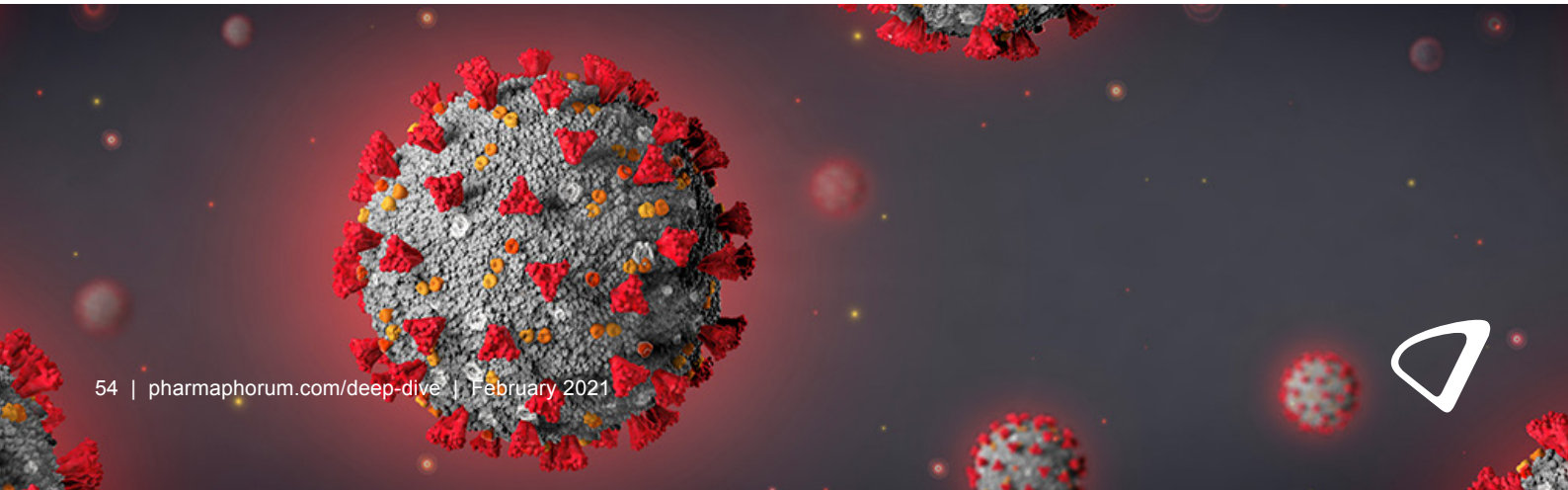
"Customer satisfaction is not a goal, it's our policy," says Mullane. "Our people really live this mission and that sometimes creates a high demand environment internally, but this is the basis on how we have grown from a small player to stand side by side with much larger organisations in just a few years."

COVID-19 vaccine innovation

For COVID-19 vaccine development, changes in media use impacted FUJIFILM Irvine Scientific before the pandemic.

"After the last flu outbreak, the World Health Organization and groups like BARDA offered to fund preparation if there could be a move from traditional vaccine methods into cell culture vaccine approaches, so we developed a suite of chemically defined serum-free vaccine media in preparation."

"We are a critical raw material to therapies and vaccines and because of that demand has been unmatched in our history. Thankfully, we invested in the expansion of our production capacity before the pandemic, so we have capacity to grow."



The company supports multiple pharmaceutical programmes within Operation Warp Speed, a public-private partnership initiated by the US government to accelerate development of COVID-19 vaccines, therapeutics, and diagnostics. Along with sister companies FUJIFILM Diosynth Biotech which is producing vaccines, and FUJIFILM Toyama Chemical which developed the antiviral therapy Avigan Tablet, the Fujifilm group of companies are providing solutions for the pandemic.

As the market continues to focus on developing efficient manufacturing operations, technology will also play a bigger role. "I think we have got some major paradigm-shifting opportunities in front of us and we are looking at all the ways we can innovate. Our parent company Fujifilm has heavily invested in this area, but we also believe that the use of data through AI is going to allow us to address some very significant opportunities for efficiency improvements in the coming years."

About the interviewee

Tim Mullane is the president & COO of FUJIFILM Irvine Scientific, which operates in the life sciences, medical device, and diagnostics industries. Tim began as a vaccine production scientist before transitioning to commercial and operational roles. He has been a C-Officer at multiple companies for the last 20 years.

About the author

Catherine Longworth is an editor and journalist, specialising in the healthcare sector. She was a reporter for Informa's Pharma Intelligence division before joining pharmaphorum in 2020.

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