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How COVID-19 has strengthened the value of the **UK life sciences industry**

The COVID-19 pandemic has put the life sciences industry into the spotlight, the UK is now able to strengthen and grow its position as a global leader.

Professor Sir John Bell GBE FRS
Regius Professor of Medicine

The UK has a remarkable opportunity to further expand its position as a global life sciences hub. Its performance in this sector over the course of the COVID-19 pandemic demonstrated how powerful the underlying life sciences base is in the UK and the ability of government, commercial organisations and academia to work together was globally unequalled.

Building a stronger UK life sciences base

The opportunity now is to consolidate on those skills and relationships to build an even stronger life sciences base here, providing more innovative interventions for healthcare, but also adding new impetus to the expansion of this economic growth sector.

The current plans for the life sciences sector, laid out in the Life Sciences Vision, illustrate the breadth of ambition in the UK's plans in this area. This vision is based firmly on the work done around the previous Life Sciences Strategy, published in 2017, which made a set of important investments in life sciences activities with the intention of growing new industries in the UK around these areas.

The current plans for the life sciences sector, laid out in the Life Sciences Vision, illustrate the breadth of ambition in the UK's plans in this area.

Focussing on population health issues

Genomics, access to healthcare data and a new approach to shifting the current healthcare paradigm to one where early diagnosis, prevention and early intervention are the key elements which were all part of the previous Life Sciences Strategy. They will all be carried on in the new Life Sciences Vision initiative and will be enhanced by a set of missions focusing on the important population health problems seen in most Western societies.

These programmes, which will utilise both investment by government and by industry, should create opportunities for industry to participate in major programmes in an integrated single-payer system which will improve their ability to innovate in these important therapeutic areas.

This will be coupled with attempts to ensure that our national regulator, the MHRA, retains its agile and effective decision making, as it did during the COVID-19 crisis and that we are able to expand and scale manufacturing, particularly biologics, vaccines and nucleic acid-based therapies.

Together, this provides an exciting platform for future economic growth and one where the UK is optimally positioned globally.

To find out more about the UK Life Sciences Vision visit: **gov.uk/government/publications/life-sciences-vision**

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Oxford Biomedica

Data security, privacy and how you deal with the knowledge that your child may have a disease for which there is no cure need to be considered.

Better outcomes start with improved **newborn screening**

As innovation in new therapeutics accelerates, newborn screening programmes need to be adapted to help ensure those who would benefit from emerging treatments can have access to them.

INTERVIEW WITH
Guillaume Favier PhD
Strategy Director, Healthcare and Life Sciences, KPMG in the UK

INTERVIEW WITH
Alasdair Milton PhD
Managing Director, Healthcare and Life Sciences Strategy, KPMG in the US

INTERVIEW WITH
Julia Krauss MBA, MPH
Manager, Healthcare and Life Sciences Strategy, KPMG in the US

WRITTEN BY
Kate Sharma

While most nations agree on the overall merits of newborn screening for inherited disorders, there's significant inequality in what they test for. Sweden tests for 24 diseases; England, Scotland, Wales and Northern Ireland – nine and France it's just five diseases.

Early diagnosis, provided it's accompanied by appropriate support, can be hugely beneficial to a patient and their family on a number of levels.

Families often wait many years for diagnosis of a rare disease. During that time, they endure a 'diagnostic odyssey' where they see one specialist after another, which can exacerbate financial strain and constant worry. If they do eventually receive a clear diagnosis, it's often too late to make a difference as the disease has progressed.

Nations may have their own criteria, but the number of conditions currently tested with a drop of blood from a baby's heel could be expanded to include additional diseases without further invasion or expense.

As Julia Krauss, Manager in Healthcare and Life Sciences Strategy at KPMG LLP (KPMG in the US), points out, "There may be an opportunity to expand the number of conditions tested by leveraging the same technology and analytes."

Patients are missing out

With the current explosion of innovation, particularly in relation to nucleic acid technologies, there's talk about treatment, but also potential cures.

Alasdair Milton, Managing Director for Healthcare and Life Sciences Strategy, KPMG in the US, points out, "If newborns are not being screened then that's a missed opportunity to intervene very early on, and we know that earlier intervention can often lead to better clinical outcomes."

For example, adrenoleukodystrophy is a condition whereby fatty acids build up in the brain causing irreversible, progressive loss of mental and physical functions.

It's believed to affect between 20 and 40 babies born each year in the UK and is not routinely screened for. However, if detected early enough, a patient could receive a potentially life-saving bone marrow transplant.

Breakthroughs in nucleic acid technologies

Breakthroughs in nucleic acid technologies, which target the underlying drivers of a disease, are already showing great promise for conditions like spinal muscular strophy (SMA) and Duchenne muscular dystrophy (DMD).

These aren't conditions that are routinely screened for in many nations, including the UK, and patients could be missing out, potentially leading to poor outcomes and, in many cases, high mortality rates.

Milton continues, "If there are no advancements in screening, we believe patients will not be able to access therapies that are available for their disease, it will be more difficult to identify patients for clinical trials for investigational therapies, and collecting valuable information on the natural history of many diseases that could help researchers develop new treatment options will be a major challenge."

Ethical considerations

In theory, with developments in genomics, a child's whole genome could be sequenced at birth identifying any number of diseases and even the child's likelihood of developing conditions like breast cancer.

Genomics England suggesting that the public widely support the idea of whole genome sequencing at birth sparks a set of new debates. Data security, privacy and how you deal with the knowledge that your child may have a disease for which there is no cure need to be considered.

In light of this, Guillaume Favier, Strategy Director for Healthcare and Life Sciences at KPMG in the UK, believes alterations to newborn screening programmes need to track with treatments, technology and the education of healthcare professionals. "At a minimum, testing should be done to detect diseases for which there are treatments or care teams in place to help alleviate symptoms and improve a patient's quality of life," he says.

If it's believed that early diagnosis leads to better patient outcomes, newborn screening should be the starting point. Revolutionary therapies are knocking on the door; and nations need to be ready to welcome them.

This article represents the views of the author(s) only, and does not necessarily represent the views or professional advice of KPMG firms. This content outlines initial considerations meriting further consultation with life sciences organisations, healthcare organisations, clinicians and legal advisors to explore feasibility and risks.

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Creating an **attractive work environment** that fosters innovation

Life sciences businesses need workspaces that attract talent and skills says Philip Campbell, Commercial Director of Oxfordshire-based science and tech cluster, Milton Park.

Why is this an exciting time for the life sciences industry?
I think the life sciences industry has always been exciting — although COVID has increased awareness of life sciences to people outside of the sector and demonstrated what the industry can quickly achieve. This has created an extra layer of excitement around the sector. Many of the companies based here have been involved in COVID-related solutions, be it testing or vaccines, so their work has become increasingly important.

What are the main considerations when choosing a place to work?
It's about being in a place with the right talent and the right skills. As real estate providers, our role is to create an environment that is attractive to talent, right down to the facilities, leisure amenities and open green spaces. Life sciences businesses also need flexibility and agility. If they are expanding, they want their landlords to be able to accommodate their complex requirements as and when necessary. A company in this sector should ask itself: 'Is our landlord set up to deal with our ever-changing needs?'

How has COVID changed people's expectations and priorities in the work environment?
COVID has accelerated changes that were already taking place. Businesses — whatever their size — are placing increasing importance on the quality of the work environment. They want and expect an environment that is better than working from home and particularly now as they seek to attract employees back into the workplace. Staff want to be surrounded by innovative, like-minded people.

For more information, please visit **www.miltonpark.co.uk**

Philip Campbell
Commercial Director, Milton Park

WRITTEN BY
Tony Greenway

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Milton Park

Finding the right support network for your business is the key to long term success

Starting any new enterprise is exciting and rewarding, but also a time of great challenge especially in a sector as complex as life sciences.

Whilst company leaders often focus on technology - people and market opportunity are often the more critical factors affecting the potential for success.

Important 'people' factors, include finding a team which serves your business needs, who have a positive track record and a shared and convincing vision, as well as appointing an experienced board populated by directors with skills that complement the executive team.

When it comes to market opportunity, is there growth opportunity, is the timing right, what is the value of the 'accessible' market, how strong is the competition and does the team genuinely understand the market and have the skill set to exploit it?

> ***Networking provides a great source of connections to highly influential people that otherwise would be difficult to find or interact with.***

Building an idea into a business
At the beginning, you don't have a business, what you have is an idea. As you progressively generate data and validate the proposition, you transform the idea into a viable company that requires substantial funding to execute.

The challenges of these early stages are often underestimated which is why on average, 82% of life sciences companies fail. It is frequently thought that the major causes of failure are technical fails, or safety issues but most are due to avoidable management mistakes. An extremely common one is poor planning and not raising sufficient funds in good time.

Value of networking
Quality networking can be vital in upskilling, tapping into advice and expertise from like-minded people in similar situations. Particularly important is to build a supportive CEO network - you need a sounding board to discuss and validate ideas in a safe environment. Networking provides a great source of connections to highly influential people that otherwise would be difficult to find or interact with.

Actively seek out the right networking events – being busy is not an excuse. Networking should be considered a fundamental and required component of any senior manager's role.

The skills and knowledge transfer, coupled with increased opportunities that quality networking present, should be embraced enthusiastically by any business manager.

For more information contact **info@obn.org.uk** to talk to a member of our team or visit **www.obn.org.uk**

John Harris
CEO, OBN (UK) Ltd

The impact of Brexit on the **movement of medicines**

The UK's departure from the European Union is having significant implications for the pharmaceutical industry. Charley Maxwell, Senior Consultant at PharmaLex explains more about the impact of Brexit and hurdles facing pharmaceutical companies.

Charley Maxwell
Director QMC / Senior Consultant, PharmaLex

WRITTEN BY
Mark Nicholls

Prior to Brexit, the EU including the UK, was one single trading block. However, shipment of medicines from Britain to the EU now requires customs declarations, additional testing and import checks before being re-released in the EU.

Similarly, suppliers to the UK can no longer sell directly from the EU. Stock must be transferred to a UK warehouse, where a UK Responsible Person for Import (RPi) conducts import checks before releasing stock. Thus impacting the just in time supply chain model previously enjoyed.

Complex rules around Northern Ireland

Supply to Northern Ireland is also complicated as different rules apply depending on the flow of goods.

GB to NI requires completion of customs declarations, sanitary and phytosanitary inspections meaning that goods flowing from GB to NI are treated similarly to goods coming into the EU from a third country.

In the other direction, manufacturers/wholesalers benefit from the Unfettered Access Procedure (UAP), introduced via the Northern Ireland Protocol, which guarantees free trade from NI to GB.

Medicine verification systems

Divergence in standards is leading to internal trade issues as demonstrated with Serialisation through the European Medicines Verification System (EMVS). Securemed - the UK-NI National Medicines Verification System (NMVS), now only allows for serialisation of packs destined for Northern Ireland, so manufacturers can no longer serialise packs for the GB market.

Similarly, there are different Adverse Drug Reaction reporting requirements and so suppliers to the UK as a whole now require two distinct stock-keeping units (SKUs) for supply to GB and NI.

The EMVS system makes medicines very difficult to counterfeit and with the UK only partially connected, there is a risk counterfeiters may target the UK. Thus, leaving it vulnerable to falsified medications entering the supply chain. The UK government has taken steps to counter this however, it may take several years to implement a UK only system to duplicate the EMVS.

To find out more about the steps being taken in the UK to remain attractive for investment in medicines research and development or to learn more about how PharmaLex can support you managing these challenges.

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Boosting the **health and wealth** of the nation

The pandemic has shown us the value of a strong life sciences sector and demonstrated what is possible when government, industry, academia and the NHS work together to overcome major health challenges.

Governments across the globe are rapidly mobilising plans to enhance their life sciences offer, seeking to attract major industrial investment and top scientific talent. If they get this right the rewards are clear – improved patient outcomes, the creation of highly skilled and highly paid jobs and greater resilience to future pandemics.

The UK Government has been quick out of the blocks by publishing the Life Sciences Vision earlier this year. It's an exciting prospectus, outlining tangible proposals which could unlock enormous potential across the whole life sciences innovation system.

The Vision identifies three focus areas

First, the NHS should play a vital role as an innovation partner. We have seen during the COVID crisis that the NHS can be a powerful driver of research as well as patient care. We need to build on this success and forge a new partnership between industry and the service – as well as with patients, regulators and other system partners. We need to ensure that the UK is not just a strong location for discovery science but is also the destination of choice for clinical development and that we attain genuinely world-leading adoption of technology.

Second, we must maintain and enhance investment in the science base. Our world-class universities, research institutes and infrastructures act as a magnet for talent and industrial investment. But, for decades we have underinvested in this science base – with public investment in R&D well below our international competitors and our overall investment in R&D at 1.7% GDP, compared to the OECD average of 2.4%. This is rightly a priority area for the UK Government with a manifesto pledge to double the science budget – we need to see this delivered on.

A third and vital precondition is harnessing the unique potential of NHS health data to drive and accelerate research. This has to be done in the right way, with transparency of purpose and a clear governance framework. But it is a unique asset for delivering improved patient outcomes which we must utilise. We must invest in the technological infrastructure, frameworks, platforms and skills needed to make the most of this unique asset.

Delivering the vision

It vital that the Government's focus now turns to delivery of the Vision, at pace and scale. If we back life sciences, they can be at the heart of improving the health and wealth of the nation, at a time when both have never been under such pressure.

Dr Richard Torbett
Chief Executive, ABPI

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Embracing the exciting future of the **life sciences industry**

Collaboration plays a vital role within the life sciences industry. By bringing together leaders from across the sector including industry, academia, government and regulators we can provide unique opportunities to identify industry challenges to find strategies and solutions.

Dr Martino Picardo, Chairman of Discovery Park, shares his predictions for the future of life sciences.

How are open innovation and collaboration being addressed in the life sciences community?
The life science community is embracing the concept of partnership and collaboration over competition. As a result, we are working towards a common goal of improving patient outcomes. Different life science centres are embracing open innovation to different extents. For example, Alderley Park, Stevenage Bioscience Catalyst and ourselves at Discovery Park appear to be to be at the forefront.

> ***The cost of bringing drugs to market is too much for most companies on their own, as the risk is too high. Sharing the load can help make the process easier.***

How does collaboration help accelerate productivity within this industry?
The cost of bringing drugs to market is too much for most companies on their own as the risk is too high. Sharing the load can help make the process easier. In order to do this, we need to embrace partnership, collaboration and in particular consortium based approaches. These approaches combine knowledge and work towards a common goal. There are some great examples of how this has worked so far, including the Dementia Consortium and the Vaccine Taskforce.

What infrastructure support is necessary to help with this?
My mantra is you require the "holy trilogy" to accelerate productivity. You need people, infrastructure and money. The demand for lab-based infrastructure is currently very high in the UK and there is a strong desire at all levels to bring manufacturing back to the UK. This will require space and strategic thinking.

What can we expect for the future of life sciences?
A bumpy but exciting ride! There has never been a more exciting time for UK life sciences. We need to continue to learn and build on our pandemic experiences. Partnerships are best and supply chains and community engagement are crucial. We need to improve the way we promote the value of science in our lives. We need more articulate and communicative scientists and ones with digital and data experience. Finally, we need to focus more and more on patient benefit.

Dr Martino Picardo
Chairman of Discovery Park, on behalf of Life Science Integrates

Supporting the convergence of **tech and life sciences**

Technology has the potential to transform life sciences – but only if we develop and nurture links between medicine, academia and business.

Image provided by Bruntwood SciTech

Dr Kath Mackay
Director of Life Sciences, Bruntwood SciTech

WRITTEN BY
Amanda Barrell

As the life sciences and technology sectors continue to converge, greater cross-sector collaboration is the key to realising the potential of the medtech revolution.

That's according to Dr Kath Mackay, director of life sciences at Bruntwood SciTech - the UK's leading property and innovation services provider to the science and technology sector. Bruntwood SciTech's network of innovation districts is currently home to more than 500 science and tech companies.

"Life science is increasingly being influenced by tech," she says, explaining that technology has the potential to solve many of the challenges faced by healthcare systems.

"We have chronic diseases with no curative treatments and the increasing cost of healthcare is something we have not got to grips with, either nationally or internationally."

Embracing new horizons

But new technologies are transforming the landscape. "The blending of life sciences and tech is hugely exciting, and there are some underpinning tools and technologies with the potential to revolutionise life sciences," says Dr Mackay.

"Drug discovery and development, for example, is well recognised as being an intensive, long and expensive process. But developments in artificial intelligence (AI) and machine learning (ML) over the last 10 years have allowed us to use bioinformatic tools to discover new targets. In 2019, the first AI-discovered drug was moved into the clinic."

Genomics, 3D printing, robotics and advanced communication solutions also have the potential to help clinicians rise to the challenges of 21st century healthcare.

Developing the solutions, however, is only half the battle. Pioneering technologies will only make a difference if they are rolled out across the NHS requiring a whole-system approach, says Dr Mackay.

"We need to get to a point where these tools are commonplace, because there really is huge potential for a revolution in many healthcare areas."

Greater collaboration between universities, hospitals and tech companies, as well as private and public bodies, is a key part of the solution, she adds.

Knowledge, proximity, collaboration

Bruntwood SciTech's latest development, Birmingham Health Innovation Campus in partnership with the University of Birmingham, aims to support the continued convergence of health and tech by creating a supportive, collaborative ecosystem.

The campus is one of six Life Science Opportunity Zones established by the Government's Department for Business, Energy and Industrial Strategy (BEIS) and has been identified by the Department for International Trade (DIT) as a High Potential Opportunity (HPO) for data-driven healthcare.

"The West Midlands offers an attractive proposition for life science companies says Dr Mackay. With a diverse, stable population of almost 6 million, it is also a world leader in both academic research and primary care and has the capability to offer the full supply chain from clinical trials through to manufacturing and logistics.

"Birmingham is recognised as a centre of excellence in areas such as paediatric medicine, advanced therapies and emergency medicine. But there isn't opportunity to grow a significant industry in the region."

There's also a lack of specialist space for businesses in the sector. Opening in 2023, the first building at Birmingham Health Innovation Campus, No1 BHIC, will offer a range of specialist lab and office space for digital health, medtech and biopharma companies. It will also be home to the University of Birmingham's Precision Health Technologies Accelerator (PHTA) and Birmingham Precision Medicine Centre providing direct access to, and relationships with, the local healthcare system.

"The campus will allow businesses to work alongside the neighbouring hospitals in areas such as health data, medicine, diagnostics, medtech and clinical trials – areas that are being driven by the convergence of life sciences and tech."

A healthcare system of the future

This level of direct access to knowledge and expertise is a win/win.

Ultimately, she says, it's about bringing people with different skills and backgrounds together to realise the potential of medicine's technological revolution – and create the healthcare system of the future.

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Find out more at
grow.bruntwood.co.uk/scitech

Cell and gene therapies – the road to personalised care

Health innovation is accelerating at an unprecedented pace. New treatments, such as cell and gene therapies, have the potential to transform the management of diseases that are currently incurable.

The number of advanced therapy medicinal product (ATMP) clinical trials in the UK continues to increase year-on-year, with 154 trials reported as ongoing in 2020, indicating more than a 20% increase from last year.

ct.catapult.org.uk/clinical-trials-database

12% of cell and gene therapy trials globally happen in the UK, and the UK is, by a considerable margin, the leading centre in Europe for the development of Advanced Therapies.

ct.catapult.org.uk/clinical-trials-database

Cell and gene therapies use the body's own cells or genes to target the cause of disease. Diseased cells from the patient are modified in a laboratory and transplanted back into the patient in minimal, short, non-invasive treatments. These therapies have the potential to treat and cure a wide variety of diseases from cancer to arthritis.

The UK is home to world-leading research and manufacturing capabilities for cell and gene therapies. Researchers across the country conduct an outsized proportion of global clinical trials in these treatments. This is in part due to widespread investment in initiatives to increase research, manufacture and uptake.

Embedding cell and gene therapy in the NHS

However, there is much more to be done to embed cell and gene and other innovative therapies as a first-line treatment choice for the NHS.

The personalised nature and complexity of these treatments mean that they are at present very expensive and create challenges for regulators. As the use of personalised medicine increases, the way we assess medicines must also adapt, considering real-world evidence alongside clinical trials.

Policymaking for the future of health

For the UK to develop its place as a leader in cell and gene therapy and prepare the NHS for these innovative treatments, policymakers must be aware of the treatments and challenges ahead. A recent Policy Connect survey of 100 MPs found that only 15% have a good understanding of cell and gene therapy and 68% knew nothing at all.

Creating policy that supports industry, regulators and the NHS workforce can make cell and gene therapies more accessible, giving more patients the option of these life-saving treatments.

Creating policy that supports industry, regulators and the NHS workforce can make cell and gene therapies more accessible, giving more patients the option of these life-saving treatments.

We stand on the brink of a revolution in health care. We must use the recovery from COVID-19 and subsequent changes to the health service to prepare for the future.

Daniel Zeichner
Chair, APPG for Life Sciences

Becky Rice
Health Policy Manager, Policy Connect

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Establishing the UK as a **cell and gene therapy** powerhouse

Action needs to be taken on skills, investment and infrastructure if we are to sustain advances made in the UK cell and gene therapy sector.

Matthew Durdy
CEO, Cell and Gene Therapy Catapult

WRITTEN BY
Mark Nicholls

The UK is an emerging powerhouse in cell and gene therapy for innovative healthcare solutions, yet there remain challenges in skills, infrastructure and investment within the sector.

In the last decade, cell and gene therapy (CGT) has developed from a handful of UK companies to more than 100, creating the largest CGT cluster outside the USA.

The country is "punching massively above its weight" in attracting and developing the global industry, says Matthew Durdy, CEO of the Cell and Gene Therapy Catapult (CGT Catapult).

Building on research to address unmet need

Prominent examples of CGTs are in treatment of leukaemia with ex-vivo cell therapy, where patient cells are modified outside the body and then returned to attack disease; or haemophilia with in-vivo treatment, where the genetic modification tools are put into the body enabling cells in the liver to create Factor 8 or 9 to address the condition.

Durdy believes many more therapies will emerge to address unmet patient needs, but there is the need to support the science, invest and create infrastructure.

"These medicines are complex to manufacture, develop and derive data from, but when they work, they make an enormous difference to patients," he says.

CGT Catapult was established to bridge the gap between scientific research and full-scale commercialisation to ensure these life-changing therapies can reach patients throughout the world.

The organisation works with partners in academia, industry and healthcare to develop new technologies and innovation.

"Our role in that is to create powerful collaborations that overcome challenges to the advancement of the sector."

Overcoming barriers through collaborations

With its people, experience, physical assets, intellectual property and capabilities, CGT Catapult is central to collaborations.

The ability to manufacture sufficient quantities of viral vector for gene therapy has been a barrier to developing these medicines. CGT Catapult has collaborated with various organisations to create a platform to develop viral vectors quickly and cost effectively. They work with industry to develop national skills development programmes to address the industry's skills gap; and are working with industry and the NHS to establish standards and training for clinical staff to accelerate clinical adoption.

The aim is to make the UK the natural home for organisations that want to develop, manufacture and supply these life changing therapeutics globally.

Paid for by **NIHR** NIHR | National Institute for Health Research

Unleashing the UK's potential of **data-enabled clinical trials**

Data-enabled clinical trials proved their worth during the COVID-19 pandemic and offer a genuine opportunity to transform clinical research.

Professor Martin Gibson MD, PhD
Clinical Director of the National Institute for Health Research (NIHR) Network for Greater Manchester

WRITTEN BY
Judith Ozkan

Many scientists and researchers are pushing for the UK to realise the potential of data-enabled trials and electronic health records (EHRs) to accelerate clinical research progress.

Professor Martin Gibson, clinical director of the National Institute for Health Research (NIHR) network for Greater Manchester says, "When the pandemic hit, the potential of using patient data to improve clinical trials became clear and helped researchers set up and run trials more effectively. The NIHR vaccines research registry is an example of what can be achieved and was set up in six weeks." Over 500,000 people have volunteered to participate in research through the registry, making it an important recruitment resource for researchers working on vaccines.

Pioneering diabetes studies

Professor Gibson's long-standing interest in the potential of EHRs within the NHS to facilitate clinical research and improve care, stems from his experience as a consultant working with diabetes. He says: "The sort of remote monitoring technology we pioneered with diabetes enabled the shift to remote trials during the pandemic and allowed us to continue to improve care and treatment."

Using NHS EHRs – which can potentially capture the longitudinal medical history of 98% of NHS users - could solve some of the patient recruitment problems common to trials. Professor Gibson says: "EHRs also give us the opportunity to recruit a wider cross section of the population and make trials more representative."

Professor Gibson also points to the success of the fully decentralised ISARIC 4C study into COVID-19 and the Relieve IBS-D trial into irritable bowel syndrome as examples of progress in remote trial delivery.

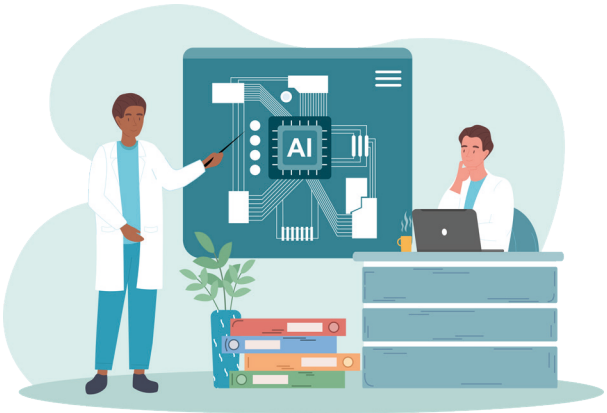
Solving privacy concerns

As a physician, researcher and self-confessed 'tech geek', Professor Gibson sees the benefits of data-enabled trials to enhance study planning, recruitment, assessment and ultimately patient benefit.

The NIHR is actively supporting work to develop UK capability to deliver trials that are suitable for data-enabled and/or decentralised models. Amongst over a dozen NIHR supported projects underway are two fully data-enabled studies into atrial fibrillation and management of asthma in children.

Despite concerns over privacy, which Professor Gibson says can be solved by good communication and informed consent, he believes the UK has proved its agility during the pandemic and can build on this to effect real progress.

Find out more at **nihr.ac.uk/industry**



Artificial intelligence: investing in new technologies in healthcare

What if machine learning and artificial intelligence could learn to detect one of the most common forms of blood cancer, through evaluating data based on the gene activity of blood cells?[1]

The biopharmaceutical industry has a long history of handling scientific and patient data and has done so for decades. However, the digitalisation of our society and healthcare systems has resulted in the creation of increasingly vast amounts of data sets, almost impossible for consistent human analysis. AI and machine learning has begun to expand our ability to analyse these increasingly large data sets, thus presenting the opportunity to rapidly develop diagnostics and therapeutics.[2]

> ***AI and machine learning has begun to expand our ability to analyse these increasingly large data sets, thus presenting the opportunity to rapidly develop diagnostics and therapeutics.***

Encouraging investments in AI

AI is still an evolving technology and this technology continues to improve rapidly. The OECD Recommendation on AI stated that governments should consider "long-term public investment and encourage private investment in R&D, including innovation in trustworthy AI."

Public investments in the collection of quality data, such as the EU Health Data Space, could allow society to input this data into the AI algorithms, allowing them to learn and grow. However, this data should not be kept in isolation and should be utilised in scientific and medical research allowing more efficient data assessments and applications, reducing the number of required physical trials and burden for patients.

Possible healthcare applications

The possibilities for the use in, and improvement of, modern health-care are immense. However, in order for people to accept the use of AI in diagnosis and treatment, they will need to be confident in its ability and security. To achieve this, the use of AI should always be ethical, compliant with data privacy laws and there should be strong governance mechanisms.

Darren Kinsella
Healthcare Biotechnology Manager, EuropaBio

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Attracting and retaining the best talent in **life sciences**

Tony Jones,
CEO, One Nucleus

COVID-19 has highlighted the strengths and value of our life sciences sector to government and society as a whole. But what will attract the talent needed for future success?

It is predicted that 133,000 new jobs will be created in the sector by 2030[1] across multiple disciplines within life sciences. Whilst the pandemic has shown the sector in an excellent light, other factors such as entry routes, career pathways, Brexit, the broader economy and technology convergence will influence whether the talented 'moths' required to fill the skills gap will be attracted to the UK light.

The Oxford-Cambridge-London triumvirate accounted for 71% of advertised life science vacancies in 2020.[2] Almost half of those vacancies were in Cambridge and in the first six months of 2021, the number has risen even further.

A destination for innovation

The clustering effect in driving innovation has long been accepted.[3] What the pandemic has shown is that remote interactions and collaborations are highly effective in the tele-connected world we now inhabit. However, innovation often arises out of serendipitous conversations that happen because innovative minds physically collide.

The proximity of complementary disciplines, such as technology, life sciences and advance manufacturing is enabling The Medici Effect. In a sector reliant on globally mobile talent, investment in creating a destination that is competitive and attractive to innovators in multiple disciplines is thus key.

Policy to practice

But it cannot all be about international mobility. Yes, to attract the best ideas and to nurture leading edge innovation, but entrepreneurs and idea-generators also need a well-equipped and trained technical workforce to deliver and scale. This is where investment in the domestic education system, career development support, infrastructure and attracting private capital are critical.

It is now incumbent on the UK Government and Trade Associations shaping the recent 'Life Sciences 10-year Vision' and 'R&D People & Culture Strategy' policy guides to demonstrate true leadership and engage all stakeholders in their delivery.

Ensuring the sector and all companies within it, including both the large corporates and 'small ships' as they have been termed when combating COVID-19, are able to buy, borrow and grow the labour pool to create, develop, manufacture and deliver the medicines and health technologies of the future is the critical next step.

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Providing additional support in the **drug development pathway**

Support companies with broad expertise are playing an important role in helping smaller firms successfully develop innovative new drugs and treatments for patients.

Developing new treatments and therapies can be a long and complex process. From concept through to therapy development, clinical trials, navigating regulatory hurdles, manufacture and marketing, all stages require extensive expertise.

While smaller companies are adept at coming up with ideas for novel therapies, and have specific expertise in some areas, a challenge lies in accessing the broader expertise to progress an initial concept through to clinical application.

This is where CDMOs (contract development and manufacturing organisations) can smooth the pathway and support the process.

Biotech start-up

Berkan Unal, Business Development Director with GenScript ProBio - the CDMO segment of GenScript Biotech Corporation - says: "We specifically help small and mid-sized biotech or start-up companies to realise their projects."

CDMOs play a critical role in helping biotech companies to optimise processes such as clinical manufacturing which can be costly in time and resources. They have become key players in the development of medical products around the world.

Senior Business Development Director Kun Yin points out: "The CDMO concept is not new, but with the boom in gene and cell therapy (GCT), demand is increasing.

"A lot of innovation is coming from academic spin-off companies, which have expertise in some areas such as drug targets, but may not be experts in the development process."

Regulatory hurdles

As a CDMO, GenScript ProBio can provide a wider service, including quality control, guidelines advice, and navigating changing regulatory hurdles, particularly on GCT, to help advance therapy and drug development for smaller firms. It can also leverage talent and provide documentation as well as physical material. A CDMO can combine support from its internal team, as well as access third party expertise for a client.

Gene and cell therapy is booming globally with developing treatments dominated by cell therapies, antivirus-based gene therapy and vaccine development.

However, challenges remain in the sector with high costs of production, materials and instruments.

But the organisation is working with clients to meet these challenges within the field of drug discovery and act as a development partner to share risk and minimise the cost.

Berkan Unal
EU BD Director, GenScript ProBio

Kun Yin
APAC & EU BD Senior Director, GenScript ProBio

WRITTEN BY
Mark Nicholls

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GenScript PROBIO

Find out more at **genscriptprobio.com**

Making a difference with disruptive **organ-on-a-chip technology**

Globally, top pharma companies are exploring the potential of organ-on-a-chip (OOC) technology to provide major improvements in the accuracy and efficiency of medicine discovery.

Dr David Hughes
CEO, CN Bio

Dr David Hughes, CEO, CN Bio Innovations

Billions are invested into drug discovery annually, yet most drugs never reach the market. Why? Because experiments fail to predict human effects. Experts suggest that bridging this gap with OOC technology will increase success rates and significantly reduce R&D costs.

> ***Now we can provide a rapid, usable, cost-effective and more human-relevant alternative.***

OOC enables us to recreate human physiology and disease. Essentially, we grow three-dimensional organs and tissues with fluid circulating through them to provide nutrients and mimic blood flow. These lab-grown mimics function and respond to drugs in the same way as in humans. They can be linked together to simulate processes such as drug absorption and metabolism, or to understand interactions between organs, such as inflammation, which drive disease and cause unexpected toxicities. To date animals, which are poor predictors of human outcomes, have been depended on to provide these insights. Now we can provide a rapid, usable, cost-effective and more human-relevant alternative.

Maureen Coleman, Chairman, CN Bio Innovations

The inability of traditional experiments to predict medicine safety and effectiveness is a root cause of drug discovery inefficiency. OOC provides high quality, human-relevant data to facilitate more informed decisions about which medicines to take into the clinic. Embedding it throughout drug discovery will undoubtedly deliver the biggest impact and greatest savings.

Opportunities to use OOC to replace animal experimentation are being explored, an area of high potential is new modalities such as cell or gene therapies, which rely on human-specific modes of action. OOC tests are demonstrating they can predict clinical outcomes that animal models cannot.

Maureen Coleman
Chairman, CN Bio

Reporter comments

- OOC is being used to cross-validate and supplement data from traditional methodologies to improve medicines discovery success rates. Its potential has piqued regulators interest, who currently work with CN Bio to support rapid and widespread adoption. From here, OOC's natural next step is its inclusion within IND submissions.
- Dr David Hughes worked with field leaders M.I.T to develop human body-on-a-chip systems. He recently published work with AstraZeneca using OOC to study fatty liver disease, a growing developed world epidemic and an area of unmet need.
- CN Bio is expanding the application of its technology across the globe and further innovation is in the pipeline

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Collaboration was key in the UK's response to the **COVID-19 pandemic**

Industry, academia and government collaboration was critical to the UK's success in procuring, developing, manufacturing and scaling up COVID-19 vaccines.

Steve Bates OBE
CEO, BIA and former member of The Vaccine Taskforce

This tripartite relationship began in February 2020, nearly four months prior to Dame Kate Bingham's appointment as chair of the UK Vaccine Taskforce (VTF) and before the agreement between AstraZeneca and Oxford University.

Scaling up vaccine manufacturing

After a request from Cath Green CBE, from the Oxford Clinical BioManufacturing Facility, the BIA galvanised its manufacturing community into a taskforce to assess UK supply chains and provide expertise to understand how to scale up, at pace, any successful COVID-19 vaccines developed by Oxford University and Imperial College London.

Key companies included Cobra Biologics, Oxford Biomedica, Pall Corporation, the Cell and Gene Therapy Catapult, Fujifilm Diosynth Biotechnologies, Centre for Process Innovation (CPI) and the Vaccine Manufacturing Innovation Centre (VMIC).

They worked day and night to support efforts to scale up vaccines for clinical trials and ultimately for delivery to patients. Ian McCubbin CBE former Vaccine Manufacturing lead on the VTF said: "There is no doubt that the BIA Taskforce created the momentum to form the UK based supply chains for the Oxford University and AstraZeneca vaccine and the Imperial RNA vaccine, which accelerated the development and scale up of the AstraZeneca vaccine in particular."

Strength of UK life sciences

This early work was essential to enable government to see the tremendous strength of the UK life sciences ecosystem and led to a domino effect of further collaborations and investments. The Government has invested in a Cell and Gene Manufacturing Innovation Centre in Braintree, CPI will be home to an mRNA vaccine library. The additional funding for VMIC will create a key UK resource for future pandemic preparedness, as will the funding for Valneva's manufacturing site in Livingstone, Scotland.

Building on these trusted and robust collaborations will be critical as we continue to build pandemic preparedness here in the UK and around the world.

UK biotechs raised a record total of £1,068 million in private capital in the three months to the end of May.

Latest investment data for biotech companies 01 March – 31 May 2021 https://www.bioindustry.org/uploads/assets/a6d48814-ac44-47d1-827f90c537e007d0/BIA-financing-update-March-May-2021.pdf

How the UK can be an **investment hub** for life sciences

Leaving the European Union has created a need for health technology regulatory change and an opportunity to stimulate innovation and technology uptake for the benefit of UK patients.

Phil Brown
Director, Regulatory & Compliance , ABHI

Indeed, these precepts are enshrined in the Medicines and Medical Devices Act, which requires a regulatory environment that is favourable to research, manufacture and provide access to health technologies.

Becoming an investment hub for life sciences is therefore based on three premises.

Global regulation

New regulatory processes should be cognisant of global data requirements. This ensures that duplication of quality, safety and performance testing is reduced as far as is practicable, whilst maintaining the expected high levels of security demanded by UK patients. This can be achieved by:

- Adopting principles detailed by the International Medical Device Regulators Forum (IMDRF), including the application of the Medical Device Single Audit Programme (MDSAP). Such adoption will drive a consistency of technical data which can be applied across multiple jurisdictions.
- Consideration of regulatory requirements in other global jurisdictions, to streamline patient access for those products already approved to recognised high standards of safety.

Future proofing

Regulatory consistency and adaptability to new technologies will ensure the future proofing of the UK market. The MHRA must develop a regulatory system that can be equally applied to devices, IVDs, digital platforms and a combination thereof, whilst ensuring relevance for many years to come.

Lack of consistency within opinions proffered by European Notified Bodies has led to criticism of the CE mark. The MHRA can address this by providing a centralised expert opinion that can be unambiguously applied by UK Conformity Assessment Bodies. This will again add to an improved level and consistency of regulatory application, particularly with regards to innovation.

Access to innovation

Improved regulatory systems will be considered moot if they are not married to similarly improved procurement processes. The UK health system has to be understanding of the regulatory process, in order to be accepting of new products. This can be achieved by increasing stakeholder input to ensure it is truly holistic and representative of the full ecosystem - beyond simply the regulator and manufacturer – to include procurement agencies, governmental bodies, surgeons and end-users.

Cell and gene therapy is adding a new dimension to the way serious diseases are being tackled in modern healthcare.

Partnerships are crucial to help get **new treatments to market**

Image provided by Oxford Biomedica

New treatments and approaches for tackling serious diseases are being developed using cell and gene therapy.

James Miskin Ph.D
Chief Technical Officer, Oxford Biomedica

WRITTEN BY
Mark Nicholls

Cell and gene therapy is adding a new dimension to the way serious diseases are being tackled in modern healthcare.

But these advanced treatments require complex research, development and manufacturing processes.

While the two are related, and to a degree interchangeable, gene therapy typically uses a genetic delivery system, such as a viral based vector, to treat a particular disease by replacing a malfunctioning gene or introducing a new gene to alleviate the disease.

Cell therapy, meanwhile, works in a similar manner but is often administered by modifying cells outside the body, with these modified cells being returned to the body to treat the disease.

Developing partnerships

James Miskin, who has more than 20 years' experience in the field, says that one of the biggest challenges lies in ensuring the technology and viral based vectors - tools commonly used to deliver genetic material into cells – are safe.

Once that has been tackled, the next challenge lies in making enough of the vector to modify enough cells to treat the disease, explains Dr Miskin, Chief Technical Officer of Oxford Biomedica, a gene and cell therapy company specialising in the development of gene-based medicines.

As the therapies are complex, Dr Miskin points to the value of developing partnerships with other organisations, joining forces to help increase the chance of a product getting to market.

"Our partners benefit from our expertise on vector and cell engineering, analytical development, process development and regulatory interactions with different agencies globally," says Dr Miskin, who joined Oxford Biomedica in 2000. He has overall responsibility for the company's quality systems, analytical testing, lentiviral-based bioprocessing development and client programmes.

"Our own internal expertise is unique in that respect because we are also a product development company and were the first to administer a lentiviral vector based product, which many of the therapies we are developing utilise, directly into patients."

Tackling disease

Many of the therapies that are developed in the cell and gene therapy (CGT) field are in the form of a chimeric antigen receptor (CAR)-T-cells. This is where T cells (one of the main immune cells in the body) are modified to recognise cancerous cells and then to attack and kill them, thereby removing the cancer.

Oxford Biomedica makes the lentiviral vector that allows that genetic modification to occur to turn T-cells into cancer killing cells. It is also developing its own CAR-T cell programme targeting a particular tumour associated antigen and working with partners on therapies that target immune system diseases.

"We are using the same type of technology for gene therapy, by delivering the vector directly to patients as opposed to a cell therapy," he says. "A good example of that is a therapy we initially developed for Parkinson's disease, now being developed by a partner company Sio Gene Therapies, which is directly administered to the brain."

COVID-19 vaccine

Oxford Biomedica also had a pivotal role in the manufacture of the AZ/Oxford COVID-19 vaccine, having joined the manufacturing consortium led by the Jenner Institute at the University of Oxford.

As the UK's biggest company specialising in viral vector development, manufacture and analytics, they had already invested in innovation and manufacturing facilities and committed to the process at an early stage.

"We just accelerated our plans," he says. "We went from never manufacturing an adenoviral vector at scale to now being the UK's largest manufacturer of them."

At the end of 2019, the company had three manufacturing suites. That has now increased to seven and it employs over 670 people, and many tens of millions of doses of the vaccine have been manufactured for AstraZeneca.

"What COVID really highlights is the importance of companies with credible capabilities," he says. "It is not just about clean rooms; you need the people, the knowledge and the expertise."

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Find out more at
oxb.com

UK science at forefront of COVID-19 discoveries

The discovery of vaccines, diagnostics and technologies to tackle the pandemic has proven the value of the UK's life sciences sector on a global stage.

Neelam Petal,
Chief Executive Officer, MedCity

The COVID-19 crisis has had a huge impact on people's lives, but with high vaccination levels, regular testing and new technologies making remote healthcare possible, we've rapidly adapted to this unpredictable new world. One thing we can be sure of is that the UK's academics, industry and clinicians have never been more at the forefront of society.

Tackling a global crisis together

The best innovations are often a product of collaboration and at the height of the global emergency, we saw people coming together across the UK to tackle a common goal. Industry and academia forged strong partnerships with AstraZeneca and the University of Oxford's development of the vaccine. The AI-powered COVID Symptom Study by ZOE with King's College London had over 4 million contributors globally. Additionally, the i-Sense partnership between UCL, London School of Hygiene & Tropical Medicine and many others received Google funding to understand the broader impact of COVID-19 using web search data.

A new dawn for diagnostics

As London's life sciences cluster organisation, we responded to the World Health Organization's request to "test, test, test" by setting up the Testing Alliance made up of London's academic and healthcare institutions and private laboratories, to create capacity for over 20,000 PCR COVID tests per day.

The UK has the fifth largest in-vitro diagnostics market in Europe and it informs 70% of all clinical decisions in the NHS, but historically there has been a lack of funding to progress new technologies. The pandemic has shown the innovation that exists in diagnostics and the health data we unlock has proved invaluable for the future of disease management and treatments.

The future of the UK's life sciences sector

The UK has long had world-class universities nurturing the next big spin-outs, top global life sciences companies and strengths in areas such as AI and advanced therapies. We have now shown the UK's value in a global public health crisis by discovering vaccines, diagnostics and technologies.

According to the BioIndustry Association, this has been a record year for investment into life sciences - with £2.39 billion raised in the year to date compared to £2.81 billion in the whole of 2020 - with deals driven predominantly by overseas investors. This will create more jobs, unleash more scientific opportunities, and make our economy more resilient. We must keep up this momentum to address future healthcare needs and cement our position as a life sciences superpower.

Expanding your **life science business** overseas

The BioIndustry Association (BIA) reported recently that the UK's biotech and life sciences sector is on the cusp of a golden age, driven by strong demand from global investors for UK innovation.

Lin Bateson
Chief Executive, BioPartner

We welcome the announcement that the UK government is increasing annual public R&D investment to a record £22 billion by launching an innovation strategy; targeting strategic technologies such as AI, bioinformatics, genomics; engineering biology, advanced materials and manufacturing.

Public R&D funding is an essential stimulus for venture capital and benefits companies of all sizes and types. Independent analysis has shown that the Innovate UK Biomedical Catalyst competition, relaunched this year, typically results in over £5 of private investment per £1 of public expenditure and increases employment by 11-15% over 3-5 years.

Investing in international growth

European start-ups tend to be less "blue sky" visionaries and are more focused on tangible targets compared to the US. We have seen that company valuations are also lower. This can be seen as an advantage as it can be attributed to EU companies being more cost-efficient and achieving targets with less funds.

> *Many of the processes that biotech and pharma developed for the COVID vaccine studies to operate with unprecedented speed, whilst never compromising on quality, are being incorporated into other programmes such as in oncology.*

Changes in regulatory framework

Now two sets of regulators are required – UK and EU, two separate regulatory and legal spaces, all must be thoroughly managed but at a cost to companies. The significant challenges encountered during drug development recognised the need for a global rethinking of the way this process is done. The ongoing pandemic has found ways to expedite the development processes. One partial solution has seen consortiums of multi-nations, academic institutions, clinicians, pharma companies and funding agencies gather at different fronts to source and manage their resources, share knowledge in real-time and the concomitant risks.

Eased regulations during the pandemic increased adoption of vaccine-related technologies in many countries, but reimbursement and regulatory policies post-COVID will be key to permanent uptake and growth.

BioPartner UK is the independent, accredited trade organisation that supports UK international trade. It is a source of advice and practical support for UK based life science organisations.

Helping put patients first in post-pandemic clinical trials

Innovative technology and lessons learned from the COVID-19 pandemic can be used to steer the future of clinical research and bolster patient participation.

Paul O'Donohoe
Senior Director, eCOA Product and Science, Medidata

Fiona Maini
Principal, Global Compliance and Strategy, Medidata

WRITTEN BY
Judith Ozkan

Much has been written about post-pandemic recovery and returning to normal but many of the disruptions experienced across the clinical research sector, notably the delay or cancellation of in-person trials, have offered up real opportunities for innovation and change.

Paul O'Donohoe, a senior director at Medidata, a clinical software platform provider and a Dassault Systèmes company, is responsible for developing the company's scientific and technical expertise for electronic clinical outcome assessments (eCOA) and mobile health in clinical trials. He says: "Many things like remote data capture, wearable devices and decentralised clinical trials (DCTs) have been around for a long time but their adoption was accelerated as a workable solution to lockdowns and restrictions due to the pandemic." This also enabled pharmaceutical companies to bring vaccines and treatments onto the market in months rather than years.

Medidata's DCT Program – the first in the world to unify direct patient data capture technology with study oversight and monitoring, representing a truly end-to-end solution on one single platform – offered researchers the chance to run a completely remote trial or a hybrid programme.

Improved patient environment

The move away from onsite attendance coupled with faster approval, adoption and availability of wearables and remote access technology improved patient involvement and engagement. O'Donohoe says: "Patient centricity is talked about so much in the industry that it has almost become meaningless, but it's really a reflection of the challenges in patient recruitment and retention. DCTs have not only increased the number of participants in terms of reach and diversity – making it possible for individuals to be involved regardless of location but have also reduced patient burden as participation is easier to fit around different lifestyles."

Lessons learned

Fiona Maini, global compliance and strategy principal at Medidata focuses on the regulatory aspects of new tech and innovation in clinical trials. She believes that lessons learned from the last two years underline how industry can advance health care through technological optimisation and prioritising digital trial solutions from a regulatory perspective. "The industry showed how quickly it was able to respond to the pandemic and we need to make sure that those lessons are not lost."

Regulatory bodies worldwide were quick to recognise DCTs and remote technology solutions such as remote monitoring and electronic informed consent (eConsent).

Maini chairs a DCT working party with the Association of Clinical Research Organisations (ACRO), established in 2019 to identify barriers to the adoption of DCTs and facilitate their implementation. She says: "A DCT approach allowed some clinical trials to continue during the pandemic which meant that patient care and evaluation could continue. By using remote strategies, we have formulated a vision and developed a toolkit for how DCTs can be planned and executed now and in the future."

Collaboration is key

Another aspect which Maini believes should be built upon is the collaboration between industry, academia and authorities. "The pandemic emphasised that collaboration is vital in addressing and establishing priorities and frameworks to face challenges that affected the whole sector."

Regulatory pragmatism won, which was particularly vital in the UK where the industry faced Brexit legislation, updated EU regulations (like the new medical device regulation) and the Medicines and Healthcare products Regulatory Agency's (MHRA) new Delivery Plan. The MHRA's Delivery Plan 2021-2023 promises a progressive agenda for the life sciences sector and its aim of putting patients first is in line with Medidata's commitment.

Both Maini and O'Donohoe are optimistic that if the industry can learn from current challenges and maintain the considerable advantages of technology that fell into place during the pandemic, the sector will be well-placed to modernise and future-proof itself.

Read more at **medidata.com**

Paid for by **Medidata**

It's time for action on **sex bias in clinical trials**

Women are less likely to be included in clinical trials but what can be done about it? Now it's time to take action.

A woman was working in preclinical safety on a new drug, which looked very safe. At the time, first time in human (FTIH) clinical trials could include employees, so she and a male colleague volunteered.

He was accepted. She was rejected, simply because she was a woman of childbearing potential (WOCBP). She felt denied the opportunity to contribute and did unpaid overtime picking up his work while he was absent, yet still receiving his usual wage plus hundreds of pounds for the trial.

A case of sexism? Not necessarily, because the regulations about WOCBP taking part in clinical trials are complex.

> ***We must encourage more of a representative segment of the population to take part, though with biological sex, there are specific trial inclusion/exclusion criteria.***

Addressing the challenges

Dr Suzanne Dilly, Chief Executive Officer at a drug development company with an ambition to bring new therapeutic options to conditions associated with Women's Health, ValiRx says: "Almost all drug development is optimised for men, due to the historic, assumed and genuine hurdles of including women in early-stage clinical trials."

"Women's health conditions are seen by drug development companies as challenging to address, because of issues getting women into trials and the variable nature of conditions due to hormone fluctuations. As a result, drug development for women's conditions, such as endometriosis, can lag behind."

The hurdles

- Companies rightly fear that unintended exposure of women in early pregnancy to a new agent could cause foetal harm.
- Historically, the UK and EU require large-scale experiments in two species of pregnant animals to show that drugs do not harm the foetus, before WOCBP can be included in clinical trials. This delays the inclusion of WOCBP and increases costs.
- With hormonal contraception, the potential for a new drug to decrease the effectiveness of the hormonal contraceptive method must be assessed before WOCBP relying on those methods can be included.
- Depending on the trial situation, some birth control methods may be preferred over others.
- Issues with the acceptance of sexual abstinence as birth control. UK regulatory guidelines require that sexual abstinence must be the usual and preferred lifestyle of the subject. Dr Stewart says: "Women prepared to abstain from sexual intercourse for the duration of a trial may not be accepted unless abstinence was their usual lifestyle choice."

Recruiting WOCBP for drug trials can be so complex that companies just restrict early trials to men.

Time for action

"More needs to be done to enable women to take part in trials, and now is the time," says Dr Jane Stewart, a specialist in reproductive toxicology at drug development safety consultancy, ApconiX. "There are now better long-acting contraceptives. Home pregnancy tests are highly sensitive and results can be submitted electronically. "

Meanwhile EU/UK regulators are adopting a softer position on the requirement for extensive pregnant animal testing prior to trials including WOCBP.

Patient-centricity

"Trials could be made more patient-centric simply by asking women what would help," says Dr Dilly. "Wearable devices could take readings on the move and clinic appointments could be within school hours, for shorter periods, with no overnight stays, balancing the logistical practicalities with safety and ethics."

She urges more public awareness of the fact that men and women are biochemically different, respond differently to some drugs and that pre-and post-menopausal women can be just as different to each other.

Other diversity criteria are equally important, trials should be designed to include all, but most diversity biases are not regulated for. "We must encourage more of a representative segment of the population to take part, though with biological sex, there are specific trial inclusion/exclusion criteria," she says.

"The opportunity to fix this is now. There's a less paternalistic attitude that empowers women to make their own decisions, and the public, as potential clinical trial participants, are more aware of the importance of drug research."

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