



How human-specific technologies
can transform lives and
supercharge the economy



Introduction

Strengthening the NHS and boosting the economy have emerged as central priorities for ensuring that people in Britain have a bright and sustainable future. Recent years have seen increasing recognition of the role that innovative, future-focused biomedical research techniques can play in this mission, such as artificial intelligence, bioinformatics and advanced human tissue cultures. The following briefing provides further details about the benefits these technologies can bring. It also puts forward strategic recommendations that will help policymakers to harness the full potential of these ethical and future-focused innovations.

The problem: a public health emergency

Major public health issues devastate lives, place immense pressure on the NHS and hold back economic growth. While many of these conditions are becoming increasingly prevalent, progress in treating them has stalled.

Case Studies

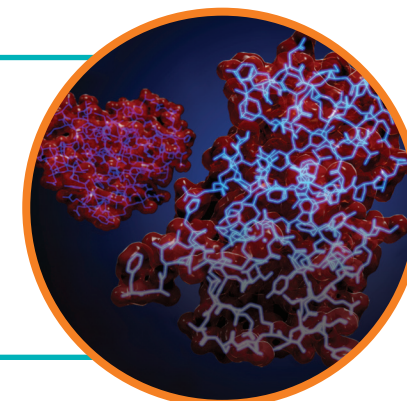
Parkinson's Disease

Parkinson's is the world's fastest growing neurological condition. Parkinson's UK estimates that around 145,000 people in the UK were living with the condition in 2020, and one in 37 people alive in the UK today will be diagnosed with it in their lifetime.¹ Researchers at Sheffield Hallam University have estimated that treating each person with Parkinson's costs the NHS £2,118 per year, while the exchequer loses £1,423 from every household that includes someone with the condition. These figures suggest that Parkinson's costs the NHS around £307 million each year, with a loss to the exchequer of around £206 million.² There is still no cure for Parkinson's and the efficacy of the main treatment, levodopa, decreases over time. This treatment dates back to more than 50 years ago, so fresh breakthroughs are long overdue.³



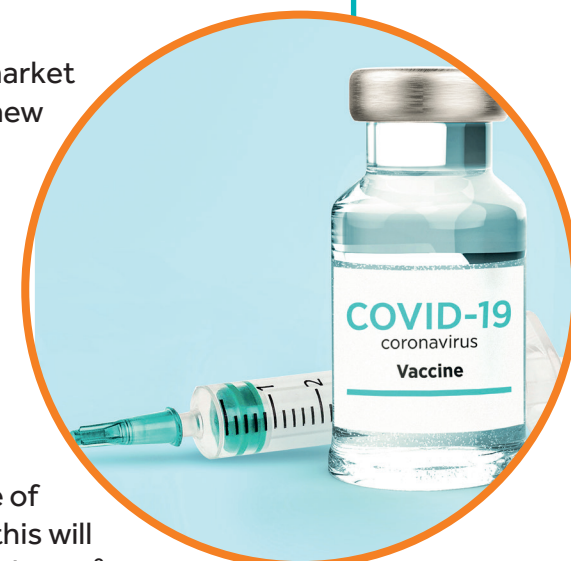
Diabetes

Diabetes UK estimates that over 4.9 million people in the UK are living with the condition. The NHS spends around 10 per cent of its entire budget on diabetes – at least £10 billion per year.⁴ Cases of diabetes in the UK could rise to as many as 5.5 million by 2030, so further progress in this field is also paramount.⁵



Challenges in bringing new drugs to market

Even when breakthroughs are made, bringing new drugs to market is challenging, slow and expensive. Since 1950, the cost of a new drug has doubled every nine years.⁶ The high rate of attrition is one of the factors that drives up the price of new drugs; around 75 per cent of research and development costs are thought to be due to drug failure.⁷ Problems in translating the results of pre-clinical tests to human patients play a major role in this high failure rate, and tests on animals are a central element of this. Over 92 per cent of drugs that show promise in animal tests currently fail to reach the clinic and benefit patients, mostly for reasons of poor efficacy and safety that were not predicted by animal testing.⁸ If the price of medicines is elevated as a result of high development costs, this will ultimately translate into higher costs for the NHS in sourcing drugs.⁹



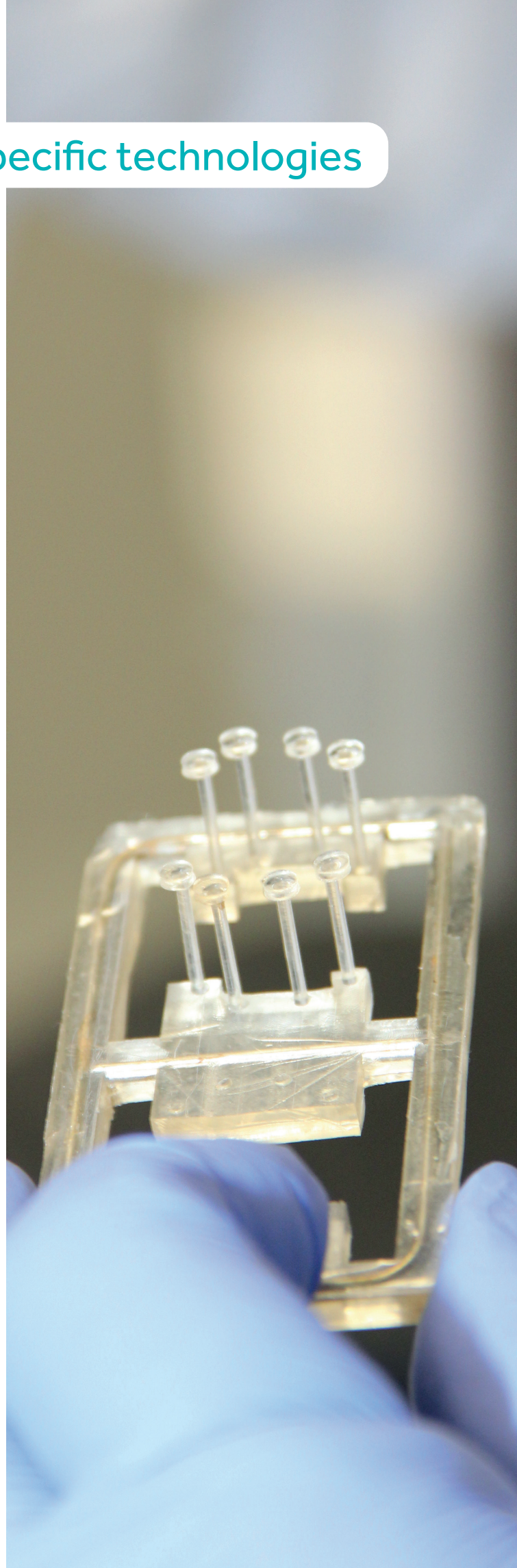
The solution: human-specific technologies

Cutting-edge, human-specific research methods can accelerate breakthroughs in tackling major diseases and provide more reliable predictions of whether drugs will be safe and effective for patients. These innovative techniques are often referred to as New Approach Methodologies (NAMs) and include the use of artificial intelligence, organ-on-a-chip and the advanced use of human cells and tissues. Since they are based directly on human biology, they are not hampered by the pitfalls of translating results from animals to people.

Securing breakthroughs in treating diseases

Proceedings from an expert workshop on the future of Parkinson's disease research concluded that 'to advance PD research, we must decisively move away from the quest for improved animal models in favor of advanced methods focused on human biology.' The experts list specific methods they would recommend, such as sophisticated models based on human cell lines; organ-on-a-chip technology; advanced imaging and computational models.¹⁰

Scientists at Animal Free Research UK's Animal Replacement Centre of Excellence at the University of Exeter have demonstrated the progress that can be made using human-specific methods. They have discovered important insights into the changes that can occur in insulin-producing cells – known as beta cells – in people with diabetes which could help protect them and find new ways to treat the condition. This breakthrough could not have been achieved using animals due to genetic differences that complicate, rather than facilitate, our understanding of human diseases like diabetes.¹¹



Professor Lorna Harries
Animal Replacement Centre of Excellence, University of Exeter

“ The crunch point for us was when we started to realise that the results we were getting with our human-relevant models were so much better than those we were getting using other techniques. ”



Professor Chris Denning
University of Nottingham

“ We know that there has been no drug produced to date that can solve the problem of heart failure in a mouse that has ever translated into the human setting. ”



Professor Valerie Speirs
University of Aberdeen

“ Being able to predict how breast cancers migrate and invade and why they do this in a particular way ... The more human relevant models that we have, the more likely we are to be able to address these questions in the future. ”

“ We're now in an era of dramatic technology development and technology through history has always driven change. I think in terms of understanding human disease and developing new treatments for human disease, we are now at a stage where we have the organs on a chip, we have the ability to print models, to print tissues. The technologies are now driving these changes. ”



Professor Mike Philpott
Animal Replacement Centre of Excellence, Queen Mary University of London



Professor Amanda Ellison
University of Durham

“ It's about putting humans at the centre of medical research, because medical research is about humans. ”

Getting safe medicines to market sooner

The risk of damage to patients' livers is one of the most common reasons why new drugs fail or are withdrawn from the market. Drug Induced Liver Injury (DILI) has caused serious harm to patients, resulting in liver transplants and even deaths. One example is the osteoarthritis drug lumiracoxib (Prexige) which was withdrawn from the UK market in 2007, following 159 reports of suspected adverse liver reactions worldwide. 91 of these reactions were considered serious, three patients required liver transplants and two sadly died.¹² Safety testing for new drugs is typically conducted on both a rodent and non-rodent species of animal, and the latter can include non-human primates and dogs. Animal tests have a poor ability to predict the risk of DILI and other harmful effects. A series of peer-reviewed scientific papers found that pre-clinical tests in animals contribute negligible weight-of-evidence to safety assurances for new drugs in humans.¹³

On the other hand, a recent study published in Nature Communications Medicine found that liver-on-a-chip technology was able to correctly identify 87 per cent of drugs that carried a risk of liver toxicity in humans, despite those drugs having passed through animal tests. These tests also correctly identified 100% of the drugs that were known not to be toxic to the liver. As well as the clinical benefits, the paper estimated that this technology could generate over \$3 billion annually for the pharmaceutical industry through increased research and development productivity.¹⁴

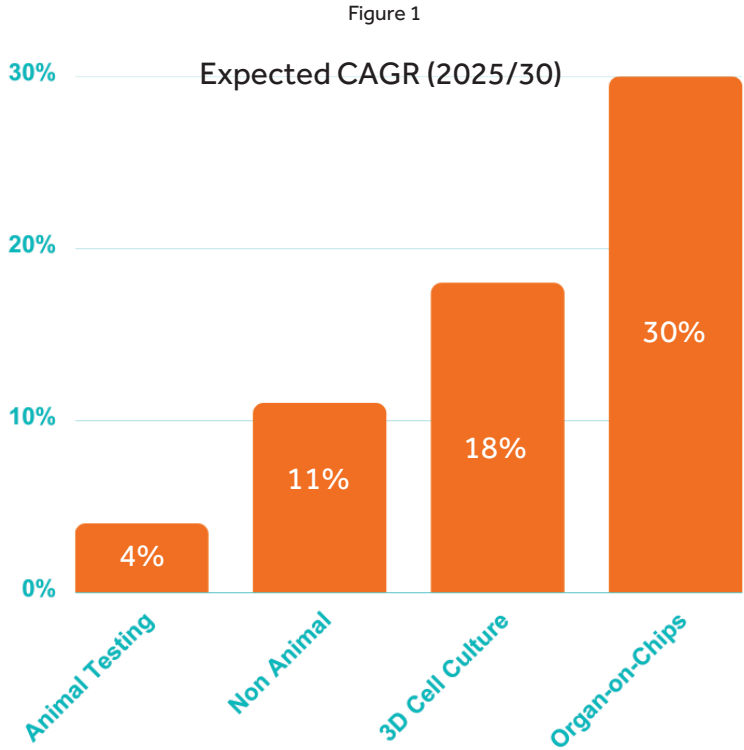


“Animal tests have a poor ability to predict the risk of Drug Induced Liver Injury and other harmful effects”

Supercharging the economy

Securing breakthroughs in tackling major public health issues will secure significant economic benefits. Finding effective treatments for major diseases will reduce pressure on the NHS and alleviate wider economic impacts, such as loss of productivity. By getting safer medicines to market sooner, these cutting-edge techniques can also reduce the drug development costs that ultimately result in higher prices for the NHS, as well as boosting the economy through increased pharmaceutical industry productivity.

In addition to these benefits, there is a fast-growing global market for human-specific technologies. With a strong life sciences industry, Britain is well placed to seize these opportunities, though bold policy action will be needed to make the most of these. Figure 1 shows the respective Compound Annual Growth Rates (CAGRs) of markets for animal and non-animal testing:

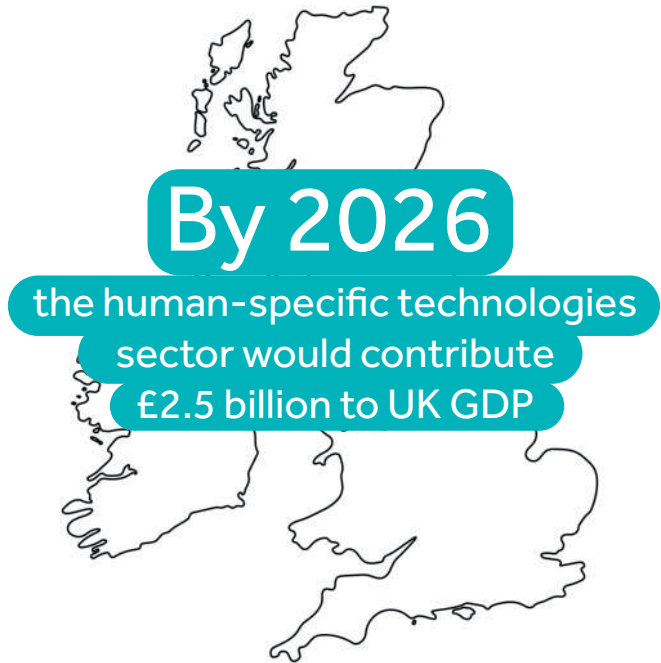


The size of the global market for non-animal testing grew from \$1.78 billion in 2022 to \$1.94 billion in 2023. The market is expected to grow at a CAGR of 10.5% to reach \$2.9 billion by 2027.¹⁵

The global market for 3D cell culture technologies grew to \$2.83 billion in 2023 at a CAGR of 18.2%. It is expected to reach \$5.65 billion in 2027.¹⁶

The size of the global market for organ-on-a-chip technology was estimated at \$62.62 Million in 2021 and is expected to reach \$386.29 Million by 2030, with a CAGR of 29.74% between 2022 to 2030.¹⁷

A 2021 report from the Centre for Economics and Business Research (Cebr) examined the size of the UK's own human-specific technologies sector and assessed how this is likely to grow over the coming years. It estimated that by 2026, the human-specific technologies sector would contribute £2.5 billion to UK GDP, which would represent an increase of 700% in the period between 2017 and 2026.¹⁸



Securing our place as a world-leader in human-specific science

While Britain has traditionally benefitted from a strong life sciences sector, decisive action will be needed to ensure that we remain a global leader in this field. Two of the top three universities for life sciences are located in the UK and the sector had a turnover of £89 billion in 2020.¹⁹ However, recent years have seen a drop in the value of pharmaceutical imports and exports in the UK, whereas most comparable countries have seen an upward trend.²⁰ This led the Chief Executive of the Association of the British Pharmaceutical Industry (APBI) to warn last year that:

“while we’ve got great strengths and enormous potential to grow life sciences in this country, we are falling behind our global competitors when it comes to crucial areas like the use of diagnostics, patient uptake of new medicines, recruitment to clinical trials and pharmaceutical exports.”²¹

Focusing on human-specific methodologies could help Britain to secure a strategic advantage as a global life sciences superpower, and while several leading human-specific technology companies are based in the UK (such as CN Bio Innovations and Kirkstall Ltd), North America represents the largest region in the non-animal testing market,²² and US regulators are leading the way in establishing relevant partnerships. Cambridge-based CN Bio Innovations, for example, has recently secured a second expansion to its collaboration with the US’s Food and Drug Administration (FDA). This latest partnership will explore how the company’s organ-on-a-chip technology can predict the level of a drug that will reach the bloodstream, which is important for determining safe doses for patients. The work will compare the use of this new technology to existing animal-based methods.²³

The FDA has published several roadmaps and strategies to support the transition to human-specific science.²⁴ In addition, Congress has now passed the FDA Modernization Act, which facilitates the use of non-animal methods within the drug testing process.²⁵

UK regulators now have an exciting opportunity to create a pro-innovation regulatory environment and embrace the benefits offered by more advanced and accurate technologies. International regulatory guidance typically generates the expectation that new drugs should be tested on two species of animal (one rodent and one non-rodent) before proceeding to clinical trials.²⁶ However, since this represents guidance rather than concrete legal obligations, there is scope for UK regulators to lead the way by allowing human-specific, non-animal methods to be used in the safety testing of new drugs. This was confirmed in evidence given to the All-Party Parliamentary Group (APPG) on Human Relevant Science by an employee of the Medicines and Healthcare products Regulatory Agency (MHRA): ‘(...) the MHRA employee confirmed that there is no requirement that animal studies be used, which was confirmed by an expert in EU and international animal law. He also stated that the MHRA accepted alternatives to animal studies, that animal studies should not be the default, and that it made this clear to all sponsors of clinical trials.’²⁷

The UK is in a strong position to align or advance; for example, the MHRA could require the inclusion of data from human-specific methods within evidence submitted on the safety profiles of new drugs.

The agency could support this work by establishing partnerships with leading UK-based biotech companies, to ensure that we are capitalising on our domestic strengths in this area.

It is also important to emphasise that there is no regulatory requirement to use animals within basic research. This means that researchers focused on exploring the underlying mechanisms and development of disease are free to exclusively use human-specific methods.

In addition, the Netherlands has long been at the forefront of pro-innovation policy on human-specific methodologies, with the government supporting cross-sector collaboration in this field, such as establishing the Transition Programme for Innovation without the use of animals (TPI).²⁸ This includes partners from government, academia, industry and the third sector, and has pioneered ‘helpathon’ initiatives that allow for a collaborative approach in addressing research questions in a human-specific way. Animal Free Research UK has recently led an initiative to pioneer the ‘helpathon’ approach in the UK.²⁹

The UK's first Helpathon

The UK’s first Helpathon supported Professor Jesmond Dalli and Dr Duco Koenis from Barts, the London School of Medicine and Dentistry and Queen Mary University of London in finding the best human models to resolve inflammation in rheumatoid arthritis and bacterial infections. It resulted in a comprehensive package of information the researchers are using to replace animals in their research. More specifically, the researchers have indicated that they will be testing Emulate’s organ-on-a-chip system and are working to transition to non-animal derived reagents.

Public support for embracing human-specific technologies

There is strong public support for Government action to promote the uptake of human-specific methods. For example, a 2021 YouGov Poll commissioned by Animal Free Research UK found that:

- 68 per cent of respondents would support a policy ending animal experiments in medical research in the UK and replacing them with non-animal alternatives (e.g. artificial intelligence and using human cells or tissue).³⁰
- 70 per cent of respondents would support animal experiments in medical research being phased out by 2040.

A 2018 Ipsos MORI survey on public attitudes to animal research, commissioned by the Office for Life Sciences, found that 75 per cent of respondents felt that more work should be done to find alternatives to animal experiments.³¹

By replacing animals in research, the use of human-specific technologies aligns with strong concern for animal welfare amongst members of the UK public. An April 2022 survey by Focalldata found that 71.86 per cent of respondents would like to see the UK Government pass more laws to advance animal welfare and prevent cruelty.³²



Policy recommendations

While future-focused technologies hold the potential to transform patients' lives and supercharge the economy, this can only be unlocked by policymakers who have the foresight and courage to take bold action.

From academia to industry, a growing number of experts are embracing human-specific technologies. Indeed, our in-depth research shows that human-focused technologies such as organ-on-a-chip, organoids, and use of human tissue, are all more likely to be cited in future scientific publications than animal methods and have a higher probability of translation to clinical impact.³³

Government policies should provide further support for this positive shift.

Since using animals in research has never been done for its own sake, many policymakers will undoubtedly agree that a full transition to human-specific methods is a desirable long-term mission, provided that the scientific, practical and regulatory supports are in place. We recommend that government policy establishes a clear commitment to look to the future by supporting this positive transition.

In the longer term, we believe that a new legislative framework could play a vital role in the transition to human-specific technologies. In the shorter term, we have identified several measures that could have a major impact in accelerating the uptake of these ethical innovations, without requiring new legislation.

Short-term recommendations: Harnessing collaboration to kickstart the transition

- **Establish a non-animal science innovation hub**

This expert taskforce would bring together representatives from government, industry, academia, venture capital and non-governmental organisations. They would work collaboratively on a pro-active transition initiative. The success of this approach has already been demonstrated by the Transition Programme for Innovation without the use of animals that was pioneered in the Netherlands.

- **Develop a cross-departmental action plan to accelerate the transition to animal-free research and testing**

One of the key activities undertaken by the innovation hub could be providing expert advice and input on the plan. This would ensure that it was both ambitious and realistic, and that the needs of different stakeholders were taken into account.

- **Appoint a minister for Human-Specific Technologies**

A new ministerial role could be established within the Department for Science, Innovation and Technology, which would be tasked with leading the transition to animal-free research and testing. This new minister would be responsible for overseeing the activities of the innovation hub, including the development of a robust action plan, and ensuring that progress is sustained and coordinated.

From academia to industry, a growing number of experts are embracing human-specific technologies

Longer-term recommendations: Establishing a legislative framework to support full transformation

Just as the Climate Change Act has supported a shift towards more sustainable and future-focused forms of energy, introducing new legislation would support the scientific community in transitioning to human-specific technologies. We recommend introducing a 'Human-Specific Technologies Act', which would provide a framework for this long-term transition.

This new legislation would establish a milestone by which it is envisaged that the transition to human-specific methods will be completed. This timeframe would be based on extensive consultation with industry and academia, to ensure it is both ambitious and realistic. Aiming for a complete transition to human-specific research methods by 2040 could be an initial starting point for further consultation.

A legislative framework of this kind could also establish key measures to be taken by policymakers, including:

- Developing and maintaining detailed and time-bound action plans
- Reporting to Parliament on progress
- Providing practical and financial support to the scientific community

This work could be supported by an expert advisory committee, and the legislation could make provision for this. Like the Climate Change Act, a 'Human-Specific Technologies Act' could also set out specific provisions that would help in the shorter term, such as using the system of Research and Development Tax Reliefs to incentivise the use of human-specific methodologies. Such legislation would place the UK firmly at the forefront of the cutting-edge, human-specific life sciences industry.

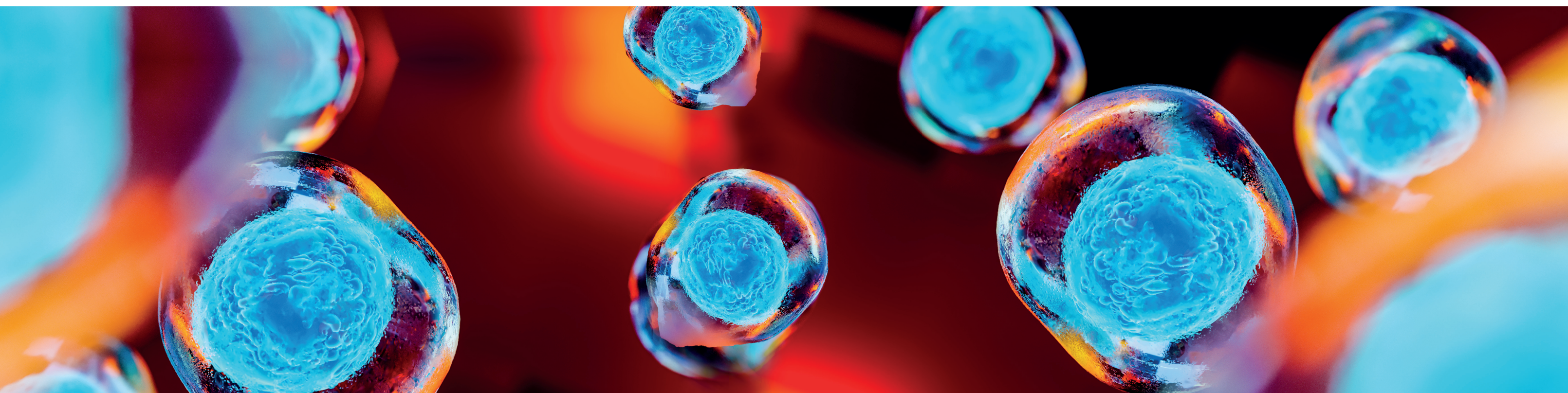
Conclusion

The UK is perfectly poised to seize the transformative opportunities offered by human-specific research methods, and bold and strategic action must now be taken to secure our position as a world-leader in this field. With the ambition and foresight to support the growth of this innovative technology, policymakers can play a central role in transforming the lives of patients around the world, while building a strong and future-focused domestic economy.



References

1. www.parkinsons.org.uk/about-us/reporting-parkinsons-information-journalists
2. <https://core.ac.uk/download/pdf/84310412.pdf>
3. www.altex.org/index.php/altex/article/view/2450/2376
4. www.diabetes.org.uk/professionals/position-statements-reports/statistics
5. www.diabetes.org.uk/about_us/news/1-10-adults-living-diabetes-2030
6. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1009577/uk-innovation-strategy.pdf
7. www.nature.com/articles/s43856-022-00209-1
8. <https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020>
9. www.kingsfund.org.uk/sites/default/files/2018-04/Rising-cost-of-medicines.pdf
10. www.altex.org/index.php/altex/article/view/2450/2376
11. www.animalfreeresearchuk.org/exeter-university-researchers-make-breakthrough-in-loss-of-insulin-producing-cells-in-diabetics/
12. www.openaccessjournals.com/articles/oseoarthritis-drug-withdrawn-from-the-uk-market-following-hepatotoxicity-fears.pdf
13. www.researchgate.net/publication/297046598_Predicting_Human_Drug_Toxicity_and_Safety_via_Animal_Tests_Can_Any_One_Species_Predict_Drug_Toxicity_in_Any_Other_and_Do_Monkeys_Help
14. www.nature.com/articles/s43856-022-00209-1
15. www.thebusinessresearchcompany.com/report/non-animal-alternatives-testing-global-market-report
16. www.thebusinessresearchcompany.com/report/3d-cell-culture-technologies-global-market-report
17. www.verifiedmarketresearch.com/product/global-organs-on-chips-market-size-and-forecast-to-2025/
18. https://www.animalfreeresearchuk.org/wp-content/uploads/2021/09/Animal-Free-Research-UK_Economic-Report-2.pdf
19. www.gov.uk/government/publications/board-of-trade-report-life-sciences/life-sciences-whats-next-for-this-top-uk-sector-a-board-of-trade-paper-web-version
20. www.gov.uk/government/publications/life-science-sector-data-2022/life-science-competitiveness-indicators-2022#international-collaboration-1
21. www.abpi.org.uk/media/news/2022/july/abpi-response-to-life-sciences-competitiveness-indicators/
22. www.thebusinessresearchcompany.com/report/non-animal-alternatives-testing-global-market-report
23. <https://cn-bio.com/the-fda-further-expands-collaboration-with-cn-bio-to-evaluate-the-physiomimix-multi-organ-microphysiological-system/>
24. www.fda.gov/science-research/about-science-research-fda/advancing-alternative-methods-fda
25. www.congress.gov/bill/117th-congress/senate-bill/5002
26. https://database.ich.org/sites/default/files/M3_R2_Guideline.pdf
27. www.humanrelevantscience.org/wp-content/uploads/APPG-report-March-2022.pdf
28. <https://www.animalfreeinnovationtpi.nl/>
29. <https://www.animalfreeresearchuk.org/first-ever-uk-helpathon/>
30. https://docs.cdn.yougov.com/9gypaorb3v/AFS_Results_210223.pdf
31. www.ipsos.com/en-uk/public-attitudes-animal-research-2018
32. https://docs.google.com/spreadsheets/d/1NPNdQpm5rSRaxNCfB-tfzdlcD_iU8as8VDKRohwPCeo/edit#gid=1912800879
33. Analysis by Animal Free Research UK, available on request



About Animal Free Research UK



Animal Free Research UK is an innovative, solutions-focused charity and our vision is a world where human diseases are cured faster with animal-free, human-specific technologies. We support researchers to develop, use and transition to these cutting-edge technologies and work with decision makers to bring about change that will benefit patients and boost economic growth, while improving animal protection. Since we were founded in 1970, we have awarded around £11.5 million to 294 novel research projects into conditions including cancer, dementia and diabetes. This has resulted in important breakthroughs, such as creating an entirely new 3D model of human breast cancer – the first of its kind.

For further information, please contact:

Isobel Martin, Public Affairs Director:

T: 020 8054 9700

M: 07935 854 231

E: isobel@animalfreeresearchuk.org



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