



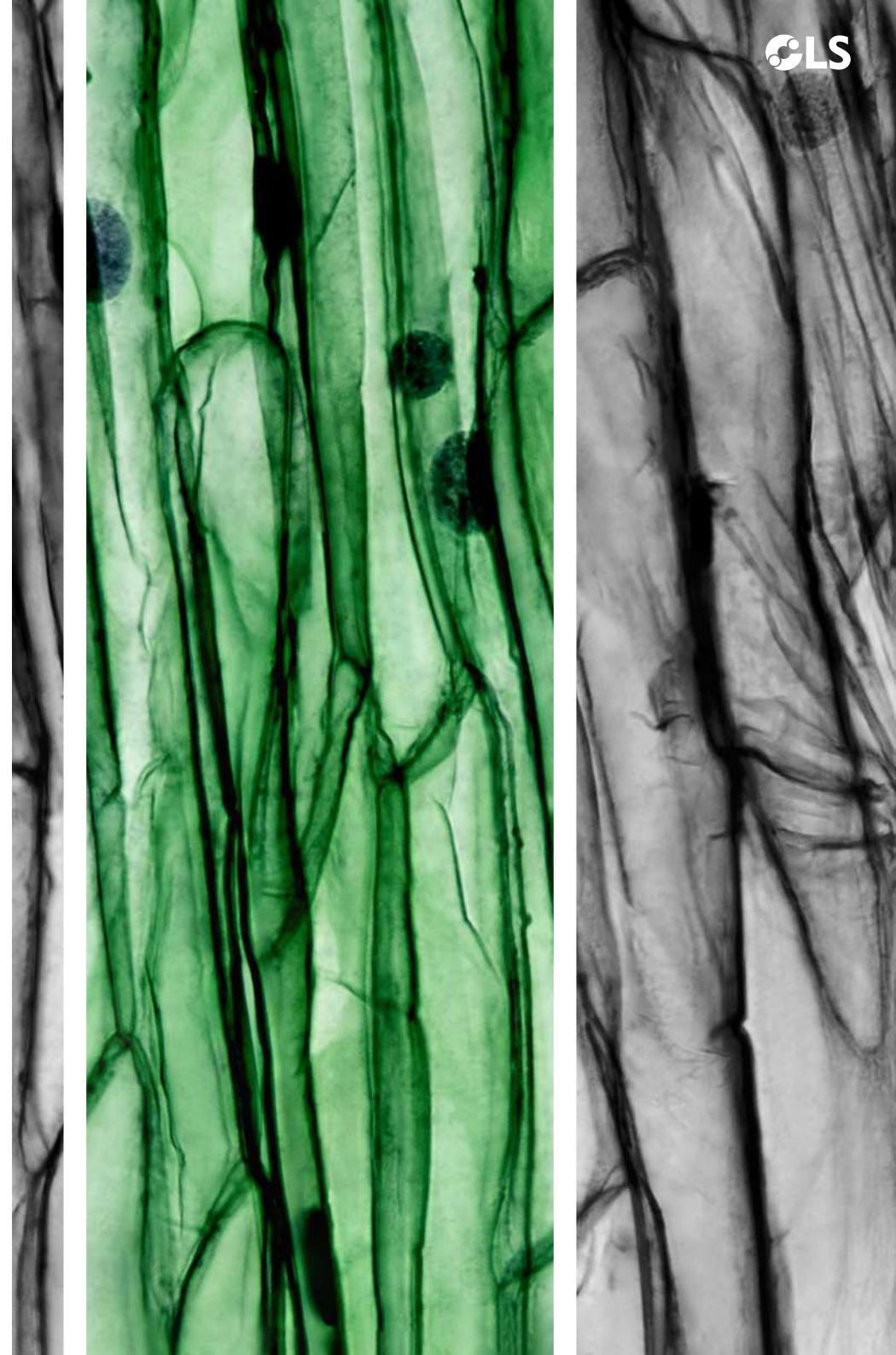
Insight: Why diversity matters -
Representation within the life
sciences industry

#clsinsights



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Executive Summary



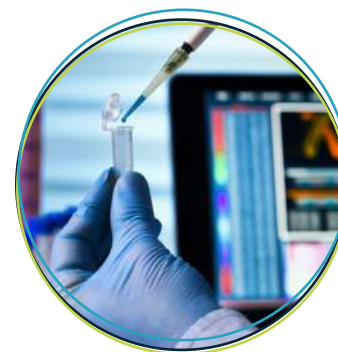
Environment, Social and Governance (ESG) and specifically Diversity, Equity & Inclusion (DE&I) are being put at the forefront of many businesses' strategic objectives; the life sciences sector is no exception.

It is vital for diversity in all its facets, to become a major focus for those that both lead and influence the industry, but it also is critical that it is a major focus area within clinical trial research for the advancement of modern medicine to continue to develop.



Lack of trust amongst ethnic communities towards participation in clinical trial participation is compounding health disparities and inequalities for underrepresented groups.

Not being provided representation in clinical trials has resulted in minority groups lacking confidence in the safety and effectiveness of a drug as evidenced in the uptake of the COVID-19 vaccination.



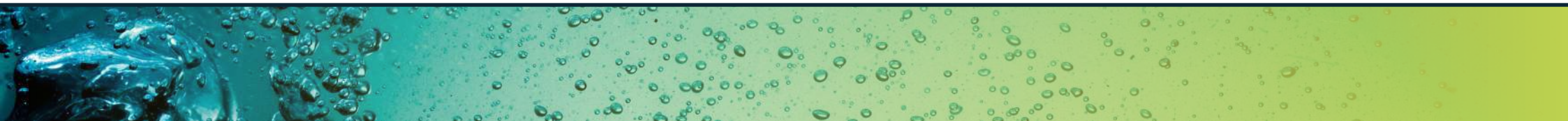
Modern medicine is evolving, with both the industry and its regulators placing a higher value on diversity and inclusion in all its facets.

More work needs to be done to ensure a level playing field, alongside the importance of science being seen as a way of benefitting all, ensuring all societal groups are included in scientific development for advancement to be truly felt.



Accreditation for women in scientific research continues to deteriorate, despite an increase in female participation in the life sciences industry.

Women are still much less likely to have accredited representation in the same way as men, despite making up 50% of the workforce; and despite an increase in female representation in STEM, the gap in papers and patents has only widened.





**It is vital for
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Introduction

Environment, Social and Governance (ESG) and specifically Diversity, Equity & Inclusion (DE&I) are being put at the forefront of many businesses' strategic objectives¹; the life sciences sector is no exception.

It is vital for diversity in all its facets, to become a major focus for those that both lead and influence the industry, but it also is critical that it is a major focus area within clinical trial research for the advancement of modern medicine to continue to advance.

¹Deloitte Analysis, 2022 Global Life Sciences Outlook, *Digitalization at scale: Delivering on the promise of science*, URL: <https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-life-sciences-sector-outlook.html>

The global benefit of US investment into clinical trials

The United States, as an example², has long made substantial investments into clinical research with the goal of improving the health and well-being of their national and international markets.

There is no doubt that these investments have contributed significantly to treating and preventing disease and extending human life, however, clinical research faces a critical shortcoming.

Currently, large swaths of the U.S. population, and those that often face the greatest health challenges, are less able to benefit from these discoveries because they are not adequately represented in clinical research studies.



²Consensus Study Report 2022, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*, URL: <https://nap.nationalacademies.org/catalog/26479/improving-representation-in-clinical-trials-and-research-building-research-equity>

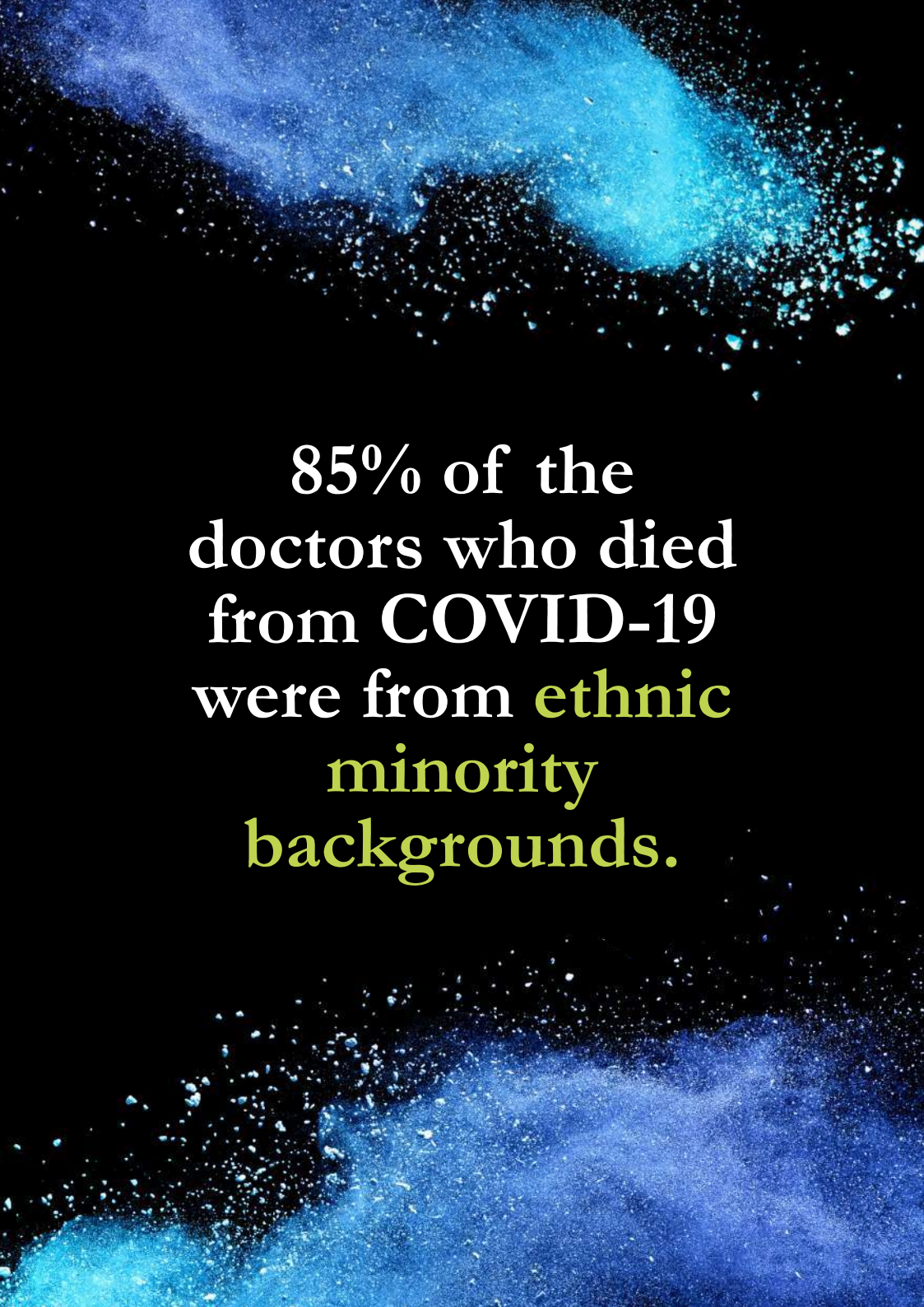
Representation from minority groups

Trust from minority groups lacking due to poor representation

While progress has been made with the representation of white women in clinical trials and clinical research, there has been little progress in the last three decades to increase the participation of racial and ethnic minority population groups.³ This underrepresentation is compounding health disparities, with serious consequences for underrepresented groups and for the nation.

This has caused major concerns about how large swathes of the population feel and are represented within new breakthroughs. Not being provided representation in clinical trials⁴ has resulted in minority groups lacking confidence in the safety and effectiveness of a drug for those populations can't be assured unless they are properly represented in the research. Examples of this could be seen with the Covid-19 vaccines where pregnant women had concerns over the vaccinations due to the lack of representation in the initial research process which has led to further research trials into this.

This extended to minority groups who were disproportionately affected by COVID, and research from the British Medical Association showed within the healthcare workforce, 85% of the doctors who died from COVID-19 were from ethnic minority backgrounds.⁵ In parallel to this the uptake of vaccines was significantly lower in minority groups to those of Caucasian backgrounds. Research which has found black people are the least likely to have the vaccine in England. Some 95% of white people aged 50 and over have been jabbed, compared with 87% of South Asian people and 73% of black people.⁶



85% of the doctors who died from COVID-19 were from ethnic minority backgrounds.

³ ibid

⁴ Wise, J, COVID-19: Study provides further evidence that mRNA vaccines are safe in pregnancy, BMJ 2022;378:o2013, URL: <https://www.bmj.com/content/378/bmj.o2013>

⁵ BMA, Race inequalities and ethnic disparities in healthcare URL: <https://www.bma.org.uk/advice-and-support/equality-and-diversity-guidance/race-equality-in-medicine/race-inequalities-and-ethnic-disparities-in-healthcare>

⁶ BBC News, Covid vaccine: How many people are vaccinated in the UK? URL: <https://www.bbc.co.uk/news/health-55274833>



Representation from minority groups

Health and safety testing minority representation

Each year, government and industry test the safety and efficacy of new pharmaceutical agents and devices before they are allowed on the market. In drug trials, one group of participants typically receives the drug, and another gets a placebo or the standard of care for the condition being studied.

Despite these tests, large swathes of the U.S. population have not been adequately represented⁷ in those studies, so clinicians lack data on new discoveries that might prevent disease and extend life in many of their patients. This includes underrepresented racial and ethnic populations; older adults; LGBTQIA+ communities; individuals with disabilities; and those who are pregnant, of reproductive age, or lactating.

Confidence in the safety and effectiveness of a drug for those populations can't be assured unless they are properly represented in the research. Although these groups would be considered minorities when broken down like that, as a collective group that is a significant number that is not represented.

⁷Goldman, D. P., Perez, E. A., and del Rio, C., *Lack of diversity in clinical trials costs billions of dollars. Incentives can spur innovation*, (August, 2022), URL: <https://www.statnews.com/2022/08/03/lack-of-diversity-in-clinical-trials-costs-billions-of-dollars-incentives-can-spur-innovation/>

Regulatory Guidance

New draft guidance from the FDA suggests that better diversity representation in clinical trials is a necessary requirement rather than a benefit.⁸ Supporting diversity in clinical trials and actually achieving this are two different issues. There is much agreement in pharma that including a broad swathe of participants in clinical trials leads to better drugs and outcomes, but most studies in the U.S. are still largely recruited from the same homogenous group. A draft guidance from the FDA aims to change that.

If there was ever any question that clinical trials had a diversity problem, COVID-19 vaccine trials erased all doubt, says Fabio Gratton, chief experience officer at THREAD,⁹ a technology and consulting service provider enabling electronic clinical outcome assessments and decentralized clinical trials (DCTs).

“You would recruit a 30,000-person vaccine trial, and within a month, you almost had it recruited, and 98% of the people were white, between the ages of 25 and 40,” he says. “Where was everybody else?”

The lack of diversity in clinical trials is due to a host of factors.

“It takes a lot more effort to search out a diverse group of participants than it does to use the usual pool of candidates. Barriers to broader inclusion range from a lack of awareness about clinical trials to inconvenient trial locations or other logistical burdens,” he says.

Another issue, and one that the FDA covers in its draft guidance, is the challenge of trust. Past abuses, such as the Tuskegee Syphilis Study,¹⁰ have also made some groups understandably cautious of research participation. However, promoting diversity is crucial to ensuring that medications are safe and effective, Gratton says because people of different races and ethnicities react to drugs differently.

⁸ FDA News Release: *FDA Takes Important Steps to Increase Racial and Ethnic Diversity in Clinical Trials: Agency's Focus on Inclusion in Trials for All Medical Products Aligns with Biden Administration's Cancer Moonshot Goal of Addressing Inequities and Beyond*, URL: <https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-increase-racial-and-ethnic-diversity-clinical-trials>

⁹ Bilodeau, K., *FDA draft guidance may turn diversity in clinical trials from nice-to-have into a must have: New guidance from the FDA will “up the ante” for diversity considerations. Here's how your company can prepare*, (May, 2022), URL: <https://www.pharmavoice.com/news/FDA-guidance-clinical-trials-diversity/623429/>

¹⁰ Centers for Disease Control and Prevention, *The U.S. Public Health Service Syphilis Study at Tuskegee*, URL: <https://www.cdc.gov/tuskegee/timeline.htm>



Reflecting Industry Standard

There is not only diversity representation that has been lacking in clinical trials, but women are also much more likely to not be credited in scientific research. A recent study by Nature has found that women are 13% less likely to be credited with authorship than men¹¹ on a scientific research paper and 58% less likely to receive credit on a patent.¹² The discrepancy exists despite survey results showing women self-report contributing to a broader swathe of types of scientific work that would merit authorship than men.

Women account for a mere 3% of Nobel Prize science category winners¹³, and then most have been jointly awarded with male peers. Only three women (Marie Curie, Barbara McClintock and Dorothy Crowfoot) have been sole prize-winners.

The study examines¹⁴ one of the most egregious author oversights in scientific history. When the structure of DNA was discovered in the 1950s, James Watson and Francis Crick crafted their model of DNA from the images obtained by fellow researcher Rosalind Franklin. Yet, Watson and Crick leap-frogged over Franklin to publish their work in a 1953 Nature paper without including her as an author.

Although we have come a long way since the canonical example of Rosalind Franklin, women are still less likely to have as much accredited representation in the same way men are given despite making up 50% of the workforce. Franklin's story may serve as a warning that rings true to young female scientists today. While the number of women in STEM fields has dramatically increased in the decades since her work, the gap in authorship between men and women on papers and patents has only widened¹⁵.

Much of this can be emphasised by the fact that women in science have a much higher dropout rate¹⁶ in comparison to men. It would, however, be beneficial to dig into the factors why and factor these into their ESG objectives. With the Life Sciences sector playing such a vital role in our everyday life, homing in on a more diverse representation with have a much more positive impact on all (Deloitte 2022).

¹¹ Smithsonian Magazine, *No Nobel Prizes for Science Went to Women This Year, Widening the Awards' Gender Gap: Fewer than three percent of Nobel science winners are women, and only one woman of color has ever received the award*, Wetzel, C., (October 2021), URL: <https://www.smithsonianmag.com/smart-news/the-nobel-gender-gap-widens-as-no-women-awarded-science-prizes-180978835/>

¹² Ibid

¹³ Huang, J., Gates, A. J., Sinatra, A., and Barabasi, A-L., *PNAS: Historical Comparison of gender inequality in scientific careers across countries and disciplines*, (February 2020), URL: <https://www.pnas.org/doi/abs/10.1073/pnas.1914221117>

¹⁴ Ibid

¹⁵ Cambridge researchers change donor kidney blood type, URL: <https://www.cam.ac.uk/stories/kidneybloodtype>

¹⁶ Ibid

The importance of diversity in blood group donation

Diversity and inclusion is not just a problem for the design and execution of trials and its outcomes. Born from a combination of culture and an inherent distrust of the industry, which may be a route cause behind why being more inclusive in trial design, there is a fundamental lack of diversity when it comes to different groups in the population. Whilst parts of the population object to donating blood, or organs due to religion, there has been a fundamental issue engaging minority groups in both donation and transplant medicine.

In a recent ground-breaking discovery by a team at the University of Cambridge, there appears to be hope for minority groups that are so heavily underrepresented when it comes to giving blood or donating organs. A new study¹⁷ has proven successful changing the blood type of three deceased donor kidneys, something which could open the possibility of universalizing organs for transplant. When accounting for the fact that ethnic minority groups typically wait a year longer for transplant than Caucasian patients, the impact could be significant on the population as a whole.

¹⁷ Cambridge researchers change donor kidney blood type, URL: <https://www.cam.ac.uk/stories/kidneybloodtype>



In 2020/21, just over 9% of total organ donations came from black and minority ethnic donors whilst black and minority ethnic patients make up 33% of the kidney transplant waiting list.

The study was focused on converting the blood group of kidneys but could prove revolutionary for a wider area of transplant medicine and was conducted by Mike Nicholson, professor of transplant surgery, and PhD student Serena MacMillan of the University of Cambridge¹⁸.

"One of the biggest restrictions to who a donated kidney can be transplanted to is the fact that you have to be blood group compatible," said Professor Nicholson.

"The reason for this is that you have antigens and markers on your cells that can be either A or B. Your body naturally produces antibodies against the ones you don't have. Blood group classification is also determined via ethnicity and ethnic minority groups are more likely to have the rarer B type. After successfully shifting blood group to the universal O type, we now need to look at whether our methods can be successful in a clinical setting and ultimately carried through to transplantation."

People from minority communities, represent low donation rates; there are simply not enough kidneys to go around. In 2020/21, just over 9% of total organ donations came from black and minority ethnic donors whilst black and minority ethnic patients make up 33% of the kidney transplant waiting list. Dr Aisling McMahon, executive director of research at Kidney Research UK¹⁹ commented on the study saying *"We know that people from minority ethnic groups can wait much longer for a transplant as they are less likely to be a blood-type match with the organs available. This research offers a glimmer of hope to over 1,000 people from minority ethnic groups who are waiting for a kidney"*.

¹⁸ Ibid

¹⁹ Kidney Research UK: <https://www.kidneyresearchuk.org/>

Conclusion

Modern medicine is evolving, and both industry and regulators are now placing a higher value on diversity and inclusion in all of its facets. Scientific discovery and research seems to be shifting to one that is becoming a more level playing field for contribution from people from more diverse backgrounds, and the value of this application is already being seen. However, the industry is by no means a level playing field and more work needs to be done to foster a research and scientific community that places value on the advancement of medicine and not from the author of the research.

Equally from an engagement perspective, a huge amount of work still needs to be done to level up the reputation of the industry and build relationships with communities across the globe. It is encouraging to see growing levels of intent, and science contributing to advancing medicine to benefit all, however for the sector to be truly inclusive, it needs to not only focus on the benefit for all, but that all feel included in its advancement.





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