

Written evidence from Wellcome (ENB0016)

Summary

1. Research into engineering biology must be underpinned by a robust, proportionate policy and regulatory framework informed by ethical norms and guidance, to ensure the field evolves in an appropriate way. The UK Government can play a key role in shaping global policy and regulation in this nascent field. By creating the conditions for a long-term stable environment in which researchers and businesses can thrive, this can enable the UK to be a leading voice globally.
2. The onward development of engineering biology is at risk unless public engagement and trust is built and nurtured as science develops. Wellcome recommends the UK Government lead an exercise to generate insights on public understanding and views of different approaches to, and applications of, engineering biology alongside wider scientific, economic, and social implications of the work.
3. Foundational discovery research must remain a priority area for the £2bn committed towards engineering biology, as it creates the bedrock on which future developments, mission-centric research and businesses are built.

Wellcome's role in enabling world-class engineering biology research in the UK

4. Wellcome is a global charitable foundation and the largest non-governmental funder of UK research, granting £820 million to UK institutions in 2023 alone. Through our work, we support science to solve the urgent health challenges facing everyone.
5. We play a prominent role as a funder for emerging engineering biology research, which is well-represented in our Discovery Research portfolio. Discovery Research is transformative research that generates new knowledge with the potential to improve life health and wellbeing.
6. Engineering biology also offers emerging opportunities in both mitigation and adaptation climate solutions to protect human health and tackling infectious diseases, linking to our Climate and Health and Infectious Diseases research portfolios. The field can play an important role in addressing these issues, for example through developing new ways to synthesise drugs against life-threatening diseases that replace those reliant on rare natural resources. However, these solutions must

be carefully considered to ensure they do not exacerbate global inequality.

7. Wellcome defines engineering biology as the integration of engineering principles and practices into biology, involving the design, construction, and testing of new biological systems to solve problems relating to human life, health and wellbeing. To us, this means manipulating biological processes to overcome challenges in human health.
8. Our approach to engineering biology encompasses all research areas that play a role in the design and testing of new biological systems. This includes considerations related to the sourcing and handling of materials of a human, animal or plant origin; the use of research models of a human or animal origin, including the development of alternatives to such models; the maintenance of infrastructure and accessibility to biorepositories; and enabling fair and open access to data of biological origin and new data processing technology and tools.
9. Wellcome has partnerships with, and provides significant funding to, several projects and key players in engineering biology. Their expertise and insight may provide the Government and the Committee with a deeper understanding of the barriers facing engineering biology research. These include:
 - a. The Francis Crick Institute: biomedical discovery institute dedicated to understanding the biology underlying health and disease.
 - b. Wellcome Sanger Institute: a world leader in genome research that applies and explores genomic technologies at scale and seeks to address some of the most difficult challenges in genomic research.
 - c. CARB-X: a global not-for-profit partnership to support the development of new antibiotics and other life-saving products to combat the most dangerous drug-resistant bacteria.
 - d. CEPI: a global partnership that aims to accelerate the development of vaccines and other biologic countermeasures against emerging infectious diseases and to ensure equitable access.
 - e. Major UK-based infrastructure projects in the areas of genomics and embryology including the UK Biobank and the Human Development Biological Initiative.

Investment in Research and Development (R&D) must be at the heart of the UK's engineering biology strategy

10. Science has the power to create transformative change for people, both here and across the globe. Foundational research is fundamental in finding solutions to urgent global challenges. Consistent support from the UK Government in this area enables the possibility for unprecedented breakthroughs that can lead to discoveries, improving health in ways we can't anticipate. Long term, this knowledge could be leveraged to develop tangible, transformative solutions to health challenges.
11. Wellcome funded one-third of the Human Genome Project, which drove advances in genomic techniques and opened a whole new scientific discipline. This project was hugely ambitious, and required the rallying support we must see around future large-scale engineering biology projects. The impact of the project was vast, leading to multiple advances in health such as: genetic testing to diagnose previously undiagnosable developmental disorders; new diagnostics and treatments for a range of cancers; and enabled technologies to be developed to track spread of infectious diseases as seen during the COVID-19 pandemic. Without this brave investment in foundational research over three decades ago, the UK would not have the leading research position and the growing industry in human genomics we see today. [A recent report from the UK Bioindustry Association](#) estimates UK firms in the area of genomics had a market cap of £5 billion and are projected to reach £50 billion by 2040.
12. The wider R&D sector also [provides value for money](#), with every £1 of public R&D spend stimulating between £1.96 and £2.34 of private spending. R&D plays a critical role in discovery and innovation, and in supporting the economy to thrive. Any financial commitment from the Government towards engineering biology must encompass foundational research.
13. We welcome the Government's commitment to spend £2bn over the next 10 years on engineering biology research in their engineering biology vision. With this funding spanning across both foundational and translational research, this provides the engineering biology ecosystem with a greater degree of stability to make long-term funding decisions, which is vital to keep pace in what is an internationally competitive field. However, to secure the long-term benefits for the UK economy, the Government must ensure that investment in foundational discovery research is prioritised.

A world-leading policy and regulatory framework is needed to provide long-term stability and growth

14. Alongside the financial commitment, we are encouraged to see a clear intention and support for policy and regulation in this area. This will support the UK in achieving a serious advantage in engineering biology, as set out in the Science and Technology Framework.
15. Research into engineering biology must be underpinned by a robust, proportionate policy and regulatory framework informed by ethical norms and societal acceptance, to support the field evolving in an appropriate way. The Government's vision focuses on responsible research and innovation (RRI) as a benefit for public consumption of engineering biology products, but in fact the benefits go much further. RRI forms a critical link between research and technological development, and wider public perception and societal expectations. Ultimately, ensuring these are aligned will provide a long-term enabling environment for engineering biology research to thrive, give businesses a clear direction to innovate with certainty, and crucially place public support and engagement at the heart of any policy.
16. Led by Baroness Warnock, [The Warnock Report](#) (1984) is a compelling example of how RRI, ethics and public engagement can change the face of a scientific discipline, earn public trust, and lead to decades of discovery. The inquiry, focused on human fertilization and embryology, emerged following the rise of IVF in the late 1970s, and the public skepticism and distrust that followed. This area was viewed with concern by the public as it appeared unregulated, in balance with the sense of pride many had for the UK's role in scientific advancement. Hundreds of submissions were received by the public, alongside organisations and scientists. The resulting recommendations led to the UK introducing a regulatory body (HFEA), and the Human Fertilisation and Embryology Act (1990). This inquiry, centered on public engagement, meant the UK public felt heard and recommendations addressed their concerns. While [this framework is now in need of modernisation](#), the Warnock Report and subsequent regulatory framework were key to ensuring embryology as a research field was able to thrive in a responsible and ethical way for the last forty years. Further, this report was widely influential across the globe, setting the tone for future policy and public discussions internationally.

17. The Government has an opportunity to engage the public and key players with the approaches, applications and implications of engineering biology. This exercise should build understanding and take a deliberative approach with key stakeholders, growing a collective understanding of opportunities and trade-offs as the science develops, thereby enabling trust and reducing barriers to research.
18. Reinforced by public trust, high regulatory standards are essential to ensuring we limit unintended consequences of emerging technologies. This is an area the UK Government has the power to change, and if delivered appropriately, would position the UK as a leading voice in engineering biology regulation and influence international standards. The UK must consider how it can increase its regulatory capacity while ensuring these methods both support the science and the public.

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