



November 19, 2021

The Biotechnology Innovation Organization (BIO) welcomes the opportunity to provide comments on the Department for Digital, Culture, Media and Sport's Public Consultation on reforms to the UK's data protection regime. BIO is a non-profit organization based in the United States with a membership of more than 1,000 biotechnology companies throughout the U.S. and from over 30 foreign countries, including the UK. BIO's members research and develop innovative health care, agricultural, industrial, and environmental biotechnology products. Over 90% of BIO's members are small and medium sized enterprises, many of whom are still pre-commercial.

The UK has acknowledged in the 2020 National Data Strategy and in the present Public Consultation how innovative solutions that make use of health data and digital technologies is driving a revolution in the healthcare space. BIO represents members who operate precisely at this intersection - harnessing big data analytics and applying sophisticated biotechnology tools and capabilities to develop cures for once incurable diseases, unleashing a new wave of biomedical innovations and driving a paradigm shift in health.

Given the lengthy history and importance of transatlantic collaborations in the life sciences between institutions in the U.S. and their partners in the UK, we have been following with interest the development of the National Data Strategy and are encouraged by the approach of DCMS to develop practical rules that enable and accelerate deeper research collaborations in the life sciences. Not only are these reforms critically important to advance the UK Government's 10 Tech Priorities but these collective efforts also have the potential to be immensely powerful drivers of public health, economic growth, innovation, and prosperity.

The international biotechnology research community stands ready to support DCMS' initiative to create an ambitious, pro-growth and innovation-friendly data protection regime that underpins the trustworthy use of data. The reforms are generally favorable to the global biotech research community and supportive of global research collaborations. For example, we acknowledge the approach by DCMS around issues such as (i) the use of broad consent for research; (ii) parameters that enable the secondary use of data for research purposes; and (iii) clarification around the standards for anonymization.

We also acknowledge the considerable attention in this Public Consultation on the significance of reliable and efficient cross-border data transfers. Ensuring the global exchange of data encourages greater global scientific R&D endeavors, leading to improved public health outcomes and driving economic growth. Efforts by DCMS to reduce barriers to responsible innovation are appreciated and recognized.



Biotech and Life Sciences Innovation Depends on Global Data Flows

The convergence of digital technologies and advances in biotechnology is unleashing a new wave of innovations, particularly from small and medium-sized enterprises (SMEs), with the potential to profoundly improve quality of life around the world. Medicine will be revolutionized by better diagnostics and cures for diseases. Food security will be improved by enhanced quality and quantity in food and feedstuffs. Our ability to respond to climate change will improve by moving the world towards biobased and zero-waste economies.

Healthcare is experiencing a major paradigm shift, from traditional one-size-fits-all medical care to personalized medicine tailored to the genomic, molecular, and lifestyle characteristics of individual patients. Unlocking the power of health care data to fuel innovation in medical research is at the heart of today's health care revolution. Medicine is increasingly a collaboration between the data science and clinical science realms. Harnessing data offers biopharmaceutical researchers deeper understanding of disease pathways and ultimately helps develop targeted treatments with improved efficacy and safety. The pipeline of biopharmaceutical innovation is rich with these transformative therapies that would not exist were it not for this remarkable convergence of modern biotechnology and the data sciences.

To realize the potential of these promising biotech innovations, life sciences researchers around the world require a robust and reliable global ecosystem for data; an ecosystem that allows for timely access to a wide range of data sets and where restrictions, if any, on international data flows should be transparent, limited in scope, risk-based, and the least trade restrictive to achieve a legitimate public policy objective.

How Restrictions on Cross-Border Data Flows Impact Biotech Innovation: Public Health and Economic Implications

Limitations on the transfer of personal data for health research purposes affect early-stage R&D efforts, clinical trial development and execution, including patient recruitment, the delivery of treatment to patients, and the assessment and reporting of potential adverse events. Collectively these restrictions may delay R&D and product development time frames which consequently add to R&D costs, may frustrate the ability for treatments to timely reach patients in need, and create challenges to obtaining meaningful pharmacovigilance and patient safety data which may compromise a company's ability to meet global medical safety reporting requirements.

Biotech SMEs and researchers in the U.S. and the UK may be significantly impacted by the lack of clear measures that enable global transfers of health data to enable life science research. Onerous mechanisms for secure and efficient international data transfers and development delays have a disproportionate impact on resource-limited SMEs, the backbone of the global bioeconomy accounting for over 70% of global clinical studies. Clear, pragmatic rules proposed



by the DCMS are welcomed by the global biotech sector and will promote scientific collaboration, investment, and the public health.

Global Society Depends on Life Science Innovation

Not only do uncertainties around the ability to transfer data abroad potentially hurt biotech SMEs around the world but, fundamentally, they do a disservice to science, which is increasingly globalized and interconnected.

Global society depends on life science innovation, especially the critical collaborations between U.S. and UK based scientists and partners, to solve some of the most pressing concerns facing humanity - the current Covid- 19 pandemic is evidence of this. Strengthening scientific cooperation between the UK and the global biotech community should be a priority and can be incentivized appropriately, without impinging on the legitimate protections of citizens' privacy rights.

Recognizing and respecting the values of privacy, security, safety, and ethics, BIO supports the efforts of the DCMS and encourages the ongoing work to create a research and innovation-friendly policy environment that enables biotech innovation and strengthens scientific collaborations with researchers around the world.

We believe that through a collaborative conversation, inclusive of private-sector voices from outside of the UK, we can develop policy solutions that support the next generation of data-driven innovations in the life sciences for the benefit of citizens in the UK and throughout the world. BIO stands ready to serve as a resource and share our perspectives from the global biotechnology community.

Sincerely,

A handwritten signature in black ink, appearing to read "J.D. Pine", is centered on the page.

Justin D. Pine, J.D., CIPP-US
Senior Director, International Affairs – IP and Data Policy
Biotechnology Innovation Organization (BIO)