The Biotechnology Innovation Organization (BIO) welcomes the opportunity to provide comments on the European Data Protection Board's ***Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data***.

BIO is a non-profit organization based in the United States with a membership of more than 1,000 biotechnology companies from almost all 50 States and over 30 foreign countries. BIO's members research and develop innovative health care, agricultural, industrial, and environmental biotechnology products. Over 90 percent of our members are small and medium sized enterprises, many of whom are still pre-commercial.

Biotech and Life Sciences Innovation Depends on Global Data Flows

The convergence of big data and advances in biotechnology, across the spectrum of the life sciences, 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, for example, 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, including human genomic resource materials as well as digital and other related type of biomedical information, to fuel innovation in medical research is at the heart of today's health care revolution. Medicine is increasingly a collaboration between 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 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 and the least trade restrictive to achieve a legitimate public policy objective.

How the EDPB Recommendations Restrict Data Transfers that Enable Biotech Innovation

The EDPB's Recommendations fall short of providing strong reassurances to the global biotechnology sector that cutting edge research and data derived from the EU will be able to support and accelerate biomedical research globally to the benefit of mankind and patients around

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the world. Providing greater clarity on the ability to transfer scientifically relevant health data out of the EU to enable scientific R&D and ensure delivery of personalized treatments to patients in the EU would be welcomed by the global scientific community.

BIO acknowledges the exemption for the transfer of pseudonymized data in Use Case 2 provides some helpful clarification with regards to biotech's ability to leverage pseudonymized data to enable R&D efforts. Although providing some relief, the life sciences sector cannot rely solely on pseudonymized data to advance their R&D and ultimately deliver personalized, potentially curative treatments to patients. This exemption purports to enable cutting edge biomedical research; however, it is limited in its ability to facilitate the delivery of cutting edge treatments to patients beyond the clinical research framework.

The Recommendations in Use Cases 6 and 7 also question, respectively, the viability of the cloud as an important tool for biotech research and the ability to access unencrypted information outside of the EU. Without the benefits of cloud-based technology or access to unencrypted data in countries outside of the EU, the ability for biotech firms around the world to gather meaningful insights and drive biomedical research forward will be significantly compromised. Cloud services that provide computing power to enable biomedical R&D has cut down the time for certain research efforts from months to mere days – which is precious time in the midst of a global pandemic. These services accelerate data sharing with partners and clinical trial development, which essentially means our sector may be able to bring innovative treatments to patients faster.

BIO encourages the EDPB demonstrate greater flexibility with the proposed approach to cross-border data flows for advancing life science research and development. We urge the EDPB take into account the context of the data transfer to advance science and improve public health through biotech innovation. We also encourage the EDPB to revisit developing proposed technical measures, such as regarding the use of cloud technologies and the access of encrypted information, that are realistic and pragmatic. We would also welcome the EDPB consider the use of certain contractual measures as sufficient safeguards to enable data transfers.

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

Impact of Data Flow Restrictions on Public Health

Limitations on the transfer of personal data for health research purposes from countries in the EU to countries out of the EU 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 delay R&D and product development time frames, 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.

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For instance, many clinical trials have adopted the use of digital tools (e.g. e-consent, e-diaries, mobile apps, etc.) that create efficiencies and enhance patient experience. Certain expertise and tools may only be found outside the EU and uncertainties around data transfer stifle the global biotech sector's ability to adopt such technologies and tools which impacts the type of data that can be collected and the speed at which it can be collected. Furthermore, due in part to inconsistent approaches across Member States regarding international transfer of patient data, clinical trial development is affected, particularly in the case where clinical trial research data needs to be processed outside of the EU by a specialized laboratory to run a genetic analysis, for example. There are many other examples about how personal data supports early stage, pre-clinical R&D efforts to determine disease pathways and explore potential cures as well as how this data impacts the ability to monitor patient's progress as they undergo innovative personalized treatments. These uncertainties taken together could ultimately delay cutting edge research and clinical development to the EU if there's not greater clarity to allow for personal data flows.

Impact of Data Flow Restrictions on EU's Emerging Biotech Enterprises

Biotech SMEs and researchers in the EU will be significantly impacted by such measures restricting the exchange of personal data to enable life science research. For example, European SMEs will have significant expenditures and allocate resources to conduct assessments on transfers abroad on a case by case basis. Given how data intensive our sector has become, this would amount to a significant logistical undertaking which puts European biotech SMEs at a competitive disadvantage globally – delaying R&D efforts, adding to an already expensive and complex scientific research program, and compromising cross-border collaborations which require timely and efficient data flows.

Creating challenges for biotech SMEs based in the EU to grow and partner globally on cutting edge research is clearly incongruent with the European Commission's broader vision seeking to establish global leadership in the sciences and cultivate a thriving innovative biotech ecosystem. The uncertainties and complexities with engaging in global R&D programs due to the restrictions on data flows could deter scientific investment in the EEA and frustrate the EU's ambitions to lead in the life sciences.

Global Society Depends on Life Science Innovation

Not only do uncertainties around the ability to transfer data abroad potentially hurt European based biotech SMEs 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 with European 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 EU and the global biotech community should be a priority and can be incentivized appropriately without impinging on the legitimate protections of EU citizens' privacy rights.

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Unfortunately, in our estimation, the relevant provisions in the draft Recommendations do not achieve this goal and frustrate the advancement of biomedical research in the EU.

Recognizing and respecting the values of privacy, security, safety, and ethics, BIO encourages the creation of a research and innovation-friendly European data policy framework that enables biotech innovation and strengthens scientific collaborations with researchers around the world. In accordance with Recital 4 of the GDPR, the processing of personal data should be designed to serve mankind – it is difficult to imagine a greater service to mankind than developing scientific capabilities to cure diseases and improve the public health through biomedical innovation.

We are encouraged that through a collaborative conversation in the context of the EU Strategy on Data and in view of Schrems II with the EDPB we can develop policy solutions that enable the next generation of data-driven innovations in the life sciences for the benefit of mankind and address current challenges while protecting fundamental privacy rights of EU citizens. BIO stands ready to serve as a resource and share our perspectives from across the fields of biotechnology.

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