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Envisioning a Trusted System for Health Data Accelerating Medical Research

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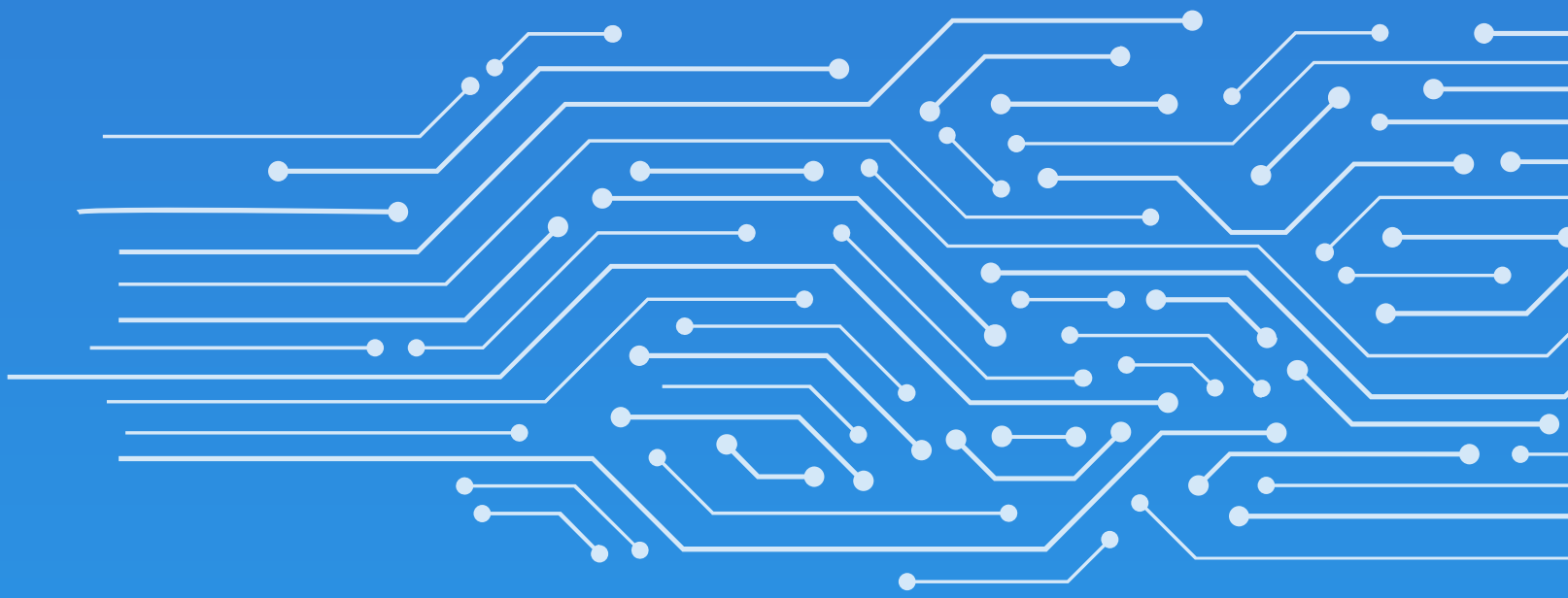

About the Milken Institute

The Milken Institute is a nonprofit, nonpartisan think tank. We catalyze practical, scalable solutions to global challenges by connecting human, financial, and educational resources to those who need them. We leverage the expertise and insight gained through research and the convening of top experts, innovators, and influencers from different backgrounds and competing viewpoints to construct programs and policy initiatives. Our goal is to help people build meaningful lives in which they can experience health and well-being, pursue effective education and gainful employment, and access the resources required to create ever-expanding opportunities for themselves and their broader communities.

About FasterCures

FasterCures, a center of the Milken Institute, is working to build a system that is effective, efficient, and driven by a clear vision: patient needs above all else. We believe that transformative and life-saving science should be fully realized and deliver better treatments to the people who need them.

Introduction

Technological innovation in the health landscape is occurring rapidly, and much of it would not be possible without patient data. Health data sets can be leveraged to build new tools that can help diagnose disease, remotely monitor and track patients, and make groundbreaking discoveries that lead to new treatments and cures. Technology companies, which have already disrupted countless industries, have the most advanced capabilities to organize data, create consumer products based on data-driven insights, and make information universally accessible in ways that are certainly applicable to the health space. However, because they have not traditionally played a central role in the health-care landscape, their participation carries substantial implications for how patient data are collected and used. This environment of uncertainty impacts patients' levels of trust and, as a result, their levels of engagement in biomedical research.

FasterCures, a center of the Milken Institute, has long been interested in engaging patients to accelerate biomedical research and innovation. With this ever-changing landscape, we are now exploring how patients' engagement with their health data can remove barriers and accelerate research. Our past work (such as our Health Data Basics project) aimed to make the role of patient data in biomedical research more comprehensible to patients, stemming from our belief that when patients can manage and control their data, they can both improve their health and help fuel advancements in biomedical research. Numerous studies demonstrate that patient input and proactive participation throughout the biomedical research lifecycle can positively impact research design, participant recruitment to studies, and study subject retention.[1] Patients' active involvement also helps ensure that research and products are relevant and essential to investigators and people affected by the diseases studied.[2] Alternatively, lack of patient participation can lead to research waste—in which scientific communities produce research findings that have minimal real-world application.[3] The evident value of patient engagement in a rapidly changing landscape of health and technology highlights the need to better understand the role of patient data in research. In this effort, the field must apply a patient-focused lens to identify the best ways for patients to contribute their data and benefit from the process. Increasingly, however, the public's lack of trust in the use of individual health data has emerged as a critical barrier, requiring proactive solutions to foster patient engagement in research.

We have already started to explore these topics in our work. In the summer of 2020, we released a report on data-driven patient participation in research, which examined its promise, described challenges to its scalability and success, and highlighted several examples of organizations and initiatives at the forefront of this effort. Following that report's release, we launched an interview series to delve into emerging trends and challenges related to patient-generated health data and patient

engagement in biomedical research. We completed 16 interviews with stakeholders across the biomedical ecosystem with expertise in creating and using patient-generated health data. This interview series helped us identify critical outstanding questions and issues. This work confirmed the need to further explore whether our system effectively enables patients to contribute to and benefit from the use of their data and whether mistrust in tech companies and inequities in data collection are hindering the acceleration of biomedical research.

In the final months of 2020, we convened an invitation-only roundtable session with more than 20 leaders and experts who work intimately with patient data in various settings. Leveraging what we identified as a foundational issue during our interview series, the session's goal was to discuss the roots of mistrust, what we might accomplish in a system where trust is the norm, and how we might achieve that vision of trust in the future. The insights that emerged from our interview series and roundtable session make it abundantly clear that trust is essential to accelerating biomedical research. To cultivate this shared vision for a trusted system, we must examine the roots of mistrust and underlying incentive structures within technology companies and medical research entities. This report discusses critical insights from our work in 2020 and outlines steps toward a trusted system for patient data.

Understanding Mistrust and Where It Comes From

Addressing mistrust in the health-care system and its collection and use of personal health data requires exploring the root causes of this mistrust. The year 2020 illuminated glaring inequities in health care and outcomes that marginalize underrepresented communities, especially communities of color,[4] and these inequities very much translate to data and digital spaces. For example, a study published in the *New England Journal of Medicine* in June 2020 found that of 13 algorithms designed to make medical decisions spanning various specialties all resulted in Black patients being less likely to receive the appropriate care.[5] Throughout the research process, the racial and ethnic composition of study populations is often skewed. *ProPublica* reports, for example, that in trials for 24 of the 31 cancer drugs approved since 2015, less than 5 percent of participants were Black, despite the fact that 13.4 percent of the US population is Black.[6]

Similarly, the CEO of 23AndMe, a major genomics company, has admitted that its product is Euro-centric and "part of the problem."[7] The marginalization and abuse of communities of color—and therefore prioritization of white and privileged populations—has long been ingrained in health-care systems and processes. This status quo has become automated and perpetuated through technological systems, including digital health tools used in research and care. Throughout our interviews,

experts confirmed a persistent failure to encourage minority groups to participate in research through invitations or incentives, as well as insufficient education about what participation in research entails. The consistent and ongoing lack of equitable engagement today is a significant contributor to mistrust.

Mistrust is also a response to how companies use sensitive health data. While the Health Information Portability and Accountability Act (HIPAA)[8] protects identifiable health records held by providers and health plans, it does not cover data entered online (such as Google searches or social media posts) and does not prevent targeted ads based on these data.[9] HIPAA also does not protect de-identified data no matter the entity, even though re-identification can be easily achieved with limited information.[10]

Another relevant and significant gap in current data protections is the lack of a comprehensive policy that prevents discrimination based on health-related data. The Genetic Information Nondiscrimination Act (GINA)[11] protects only certain data types (specifically genetic data); it does not, for example, protect information posted online, which may be provided to commercial entities. According to our interviewees and roundtable participants, this lack of clear protections is concerning for patients, leading them to fear that health plans or potential employers could leverage health-related data in their future decision-making, for example. Further, companies that collect and use data often do not provide clear and transparent information in plain language that explains how health data will be used; instead, the dense legal language specifying terms and conditions often serves as "consent." Uncertainty around companies' motives for collecting data can impede creating an environment of trust and shared values.

Still, technology companies' capabilities to organize and analyze information could be applied to great effect to help patients manage and understand their health and to create tools to help diagnose, treat, and cure conditions. However, progress will be hindered in a system that does not garner trust. For example, according to a Pew Research survey conducted in June 2019, 45 percent of US adults believe it is unacceptable for social media companies to monitor users' posts for signs of depression to identify people at risk of self-harm and connect them to counseling services. Similarly, 35 percent of US adults believe it is unacceptable for fitness tracking app makers to share user data with medical researchers to explore the link between exercise and heart disease.[12] This mistrust causes people to oppose the practice of companies using health-related data for initiatives, even those that might teach us more about health and inform and benefit patients and consumers.

An essential next step is collaborative work to create and communicate a shared vision for a trusted system, one that all stakeholders in the wider community, from patients to companies to researchers, would be intrinsically motivated and incentivized to help build.

A Shared Vision for a Trusted System

To move toward a system that patients trust, we must paint a clear picture of the desired system. The Edelman Trust Barometer, which surveys consumer trust broadly, shows that being purpose-driven and presenting a vision for the future that consumers share is a crucial component of trust.[13] In the health context, a shared vision for a trusted system should be multifold. On the one hand, it should demonstrate that companies and regulators have carefully considered and taken steps to address risks that patients might face when relinquishing their data; on the other, it should cultivate and communicate the benefits that patients would reap as a result of their participation. Steps toward this vision are outlined below.

1. **Ensure that patients reap some benefit from contributing their data.** Researchers and companies should explore ways to provide patients with personalized insights gleaned from their health data to help them better understand their health and make decisions about their care. An appropriate starting point is to first consider what data might help patients navigate their health and care, and then consider how to leverage that same data to fuel research as a next step. Such a strategy would help build trust by demonstrating to patients the value they would glean from participating. Further, directly addressing patients' unmet needs would catalyze meaningful advances in biomedical research.

2. **Establish strong and clear protections for patient data.** Demonstrating thoughtful and intentional work to address the many and multifaceted risks to sharing personal health data is an integral part of building trust. Companies that collect and use health data should carefully determine what data may be obtained pursuant to informed consent agreements and establish processes to ensure that these agreements comply with appropriate regulations and function correctly. If, given the circumstance, explicit consent is waived,[14] concrete measures should be in place to ensure that patients know their rights and receive clear, frequent information. Structural data protections should support these efforts; if HIPAA does not fully protect the data used, other guardrails should be established to prevent misuse. In addition, because data are already being transferred and shared in countless settings, enacting comprehensive legislation at the federal level to prevent discrimination would be an essential step toward building trust and meaningfully safeguarding patients from potential harm. If managed correctly, these protective measures could help fuel research and enable patients to connect freely, contributing to progress within patient communities.[15]

3. **Create safe, trusted platforms and spaces for peer groups and local communities to come together.** Clear evidence confirms that people are likely to trust their peer groups and local communities. The Edelman Trust Barometer found, for example, that the public rated "a person like myself" to be one of the most credible sources of information about companies or organizations, rated behind only company technical experts and academic experts.[16] In the context of health information, research on online peer-to-peer interactions between patients has explored how patients seek health information online. According to a 2018 survey, greater than 90 percent of young adults who received health-related information from their peers found it helpful.[17] Research has also shown that solutions surface when patient communities have a common forum to discuss ideas, problems, or unmet needs freely. These solutions can then be translated and integrated into the broader health-care market as demand grows, as has happened within the diabetes community with innovation around continuous glucose monitors.[18] Examples such as this one highlight the importance of trusted platforms and spaces that allow patient-led communities to connect openly and comfortably, without fears of their information being exploited. More generally, they serve as a reminder of the importance of patient- and community-centered approaches to spurring innovation.

   Patients already participate in various communities, such as disease organizations created by and for patients and their families and caregivers. These organizations are trusted sources of information and stewards of patient data, such as disease-specific registries, and can serve as important vehicles for partnerships with other types of organizations and research entities. Researchers can proactively seek partnerships with such organizations to better understand what unmet needs and research priorities are most important for patients and how existing data resources can be leveraged to address those needs. Many recommendations and resources for such partnerships are available in FasterCures' series of reports from 2019 on "Patient Organizations as Research and Data Partners."[19]

Ongoing work is necessary to piece together how a patient- and community-centered approach could be realized at scale for partnerships. This is a difficult task when larger companies use massive data sets encompassing tens or hundreds of millions of patient records to answer research questions or identify patterns. Furthermore, many smaller companies leverage the infrastructure and software of preeminent platforms because they do not have the resources to create new software from scratch, which challenges their ability to ensure that patient information remains contained within that community's "walls."

Ultimately, best practices, protections, and commitments must be adopted at scale to protect health information. This would help enable patient communities to trust the platforms on which they share their data in hopes that it could be genuinely used to benefit them and patients like them.

A Path Forward

Through our research, interviews, and convenings throughout 2020, we explored in depth the factors that shape how companies and researchers use patient-generated data and how patients perceive these practices. FasterCures firmly believes that patient data are a highly promising tool that can accelerate biomedical research. Therefore, we are committed to work that openly addresses existing health disparities, incentive structures, and biases to reimagine platforms, environments, and partnerships so that patients are willing participants in biomedical research. We hope that this report has illustrated the importance of trust and presented some proactive steps to help build trust. The themes discussed in this report will be explored at length throughout our upcoming work, including virtual convenings with patients and technology companies to establish responsible practices, webinars featuring key thought leaders, and actionable guidance that focus on the foundations of building trust.

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