



MILKEN
INSTITUTE

Advancing Models of Patient Engagement: Patient Organizations as Research and Data Partners

PART I: MAKING THE CASE



About the Milken Institute

The Milken Institute is a nonprofit, nonpartisan think tank.

For the past three decades, the Milken Institute has served as a catalyst for practical, scalable solutions to global challenges by connecting human, financial, and educational resources to those who need them. Guided by a conviction that the best ideas, under-resourced, cannot succeed, we conduct research and analysis and convene top experts, innovators, and influencers from different backgrounds and competing viewpoints. We leverage this expertise and insight to construct programs and policy initiatives.

These activities are designed 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.

©2019 Milken Institute

This work is made available under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported License, available at <http://creativecommons.org/licenses/by-nc-nd/3.0/>

Contents

Introduction.....	1
I. Clinical innovation is changing	2
II. An explosion of data is creating opportunities.....	3
III. Infrastructure for sharing is growing	5
IV. Patient-generated health data should be included.....	6
V. Recommendations.....	7
About the Authors	12
Acknowledgments	13

Introduction

Data sharing has become like “motherhood and apple pie” in the biomedical research and development (R&D) ecosystem. There is nearly universal agreement that aggregating and re-analyzing shared data can lead to more and better scientific insights. Funders are requiring data sharing in greater numbers, and patients are increasingly dismayed to discover that their data are not routinely shared to further research or to improve their care.

Although data from randomized controlled trials remain the gold standard for research into the efficacy of treatments, effectiveness research and new opportunities to use real-world data from electronic health records, mobile health devices, registries, claims, and other sources are receiving increased attention. As part of this change, there is an emerging focus on engaging with patients in the definition of research questions and meaningful outcomes, as well as on re-examination of the role of patient-generated health data (PGHD) within the expanding yet still fragmented data ecosystem.

In this environment, shared data networks and platforms are springing up with increasing regularity, some of them quite large in scale, bringing together Big Data on millions of patients that can be queried for research purposes.

FasterCures, alongside other patient-focused advocacy organizations, has long worked with stakeholders such as product developers and regulators to define and implement the “how to” of patient engagement. This series, “Advancing Models of Patient Engagement: Patient Organizations as Research and Data Partners,” seeks to identify effective ways for research organizations of all types, including research data networks, to partner with patient organizations that can bring patients’ perspective, participation, and data to the table. Part I of the series offers recommendations for patient organizations, researchers, and funders (who play a critical role in setting expectations and incentives as well as building capacity to enable this evolution).

KEY TAKEAWAYS FROM THIS SERIES

I.

Clinical innovation is rapidly becoming more patient-centric and data-rich.

II.

An explosion of data has opened new opportunities to capture a fuller patient experience.

III.

Infrastructure for sharing, aggregating, and analyzing data from a variety of sources is growing.

IV.

Patient-generated health data are generally not available in the environment of shared data networks—but, ideally, they should be.

I. Clinical innovation is rapidly becoming more patient-centric and data-rich.

Two paradigm shifts are unfolding in parallel and are intersecting:

1. The engagement of **patients** as partners, no longer just subjects, across the continuum of research, development, and care
2. The explosion of available **data** of all types to inform clinical research and care, and the advent of advanced analytics to help make sense of it all

Patient organizations¹ have a wide range of goals, capabilities, and resources, but at their core have been established to help current and future patients by raising awareness, ensuring robust investment in medical research, and advancing solutions that support innovation and access to effective preventive and treatment interventions. Patient organizations have funded basic discovery, preclinical, and clinical studies, and, in some cases, have created new data repositories to support and advance research in their respective areas.

FasterCures has a long history, through its TRAIN (The Research Acceleration and Innovation Network) initiative and its Patients Count program, of supporting and learning from innovative patient organizations that want to follow a more strategic and entrepreneurial approach to their role as funders and intermediaries for patient engagement in research and product development. In increasing numbers, these groups want to bring richer, real-world data about patients' lived experience to the planning and conduct of research to more quickly and accurately

answer questions that matter to patients. And their unique contribution to achieving this goal is their access to patients.

1. For the purposes of this project, we define "patient organizations" as nonprofit, philanthropic, disease-focused organizations that support some combination of research, advocacy, and education.



II. An explosion of data has opened new opportunities to capture a fuller patient experience.

With the rise of “big data,” the digital revolution, and the increase in analytics to answer pressing questions with larger and richer datasets, the data landscape has expanded exponentially.

The ability to better understand patients’ journeys and give context to claims data and other routinely collected data is pushing researchers, product developers, providers, regulators, and other stakeholders to use *all available data* to accelerate product development, inform regulatory decision-making, and impact innovation in care delivery. Data about patients’ experiences outside the clinic are not only “nice to have” but also critical to understanding and improving those outcomes. A great deal of momentum surrounds the application of new technologies, such as mobile devices and other digital platforms, to both deliver care and generate real-world data on patients’ experiences.

A critical source of such context-informing data is PGHD, defined by the Office of the National Coordinator for Health Information Technology (ONC) as “health-related data created, recorded, or gathered by or from patients (or family members of other caregivers) to help address a health concern. PGHD include but are not limited to: health history, treatment history, biometric data, symptoms, lifestyle choices.² As the value of real-world evidence increases, patient data collected from patient registries, smartphone apps, wearable devices, online communities, and social media provide new windows into the patient experience. Inputs such as patient preference studies and patient journey maps

help draw a more complete picture of the impact of disease and therapies and give context to other data. This evidence can be used to align unmet medical need with targets, as well as to identify barriers to participation in research and access to care critical to illuminating and understanding the full picture.

Patient organizations can be sources of PGHD, and, while not the only source, they are available and increasingly enthusiastic partners, trusted intermediaries with patients, and funders for the collection and sharing of this type of data. And some are performing these functions in very sophisticated and influential ways.



2. Office of the National Coordinator for Health Information Technology, “What are patient-generated health data?” HealthIT.gov, <https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data> (accessed September 26, 2019).

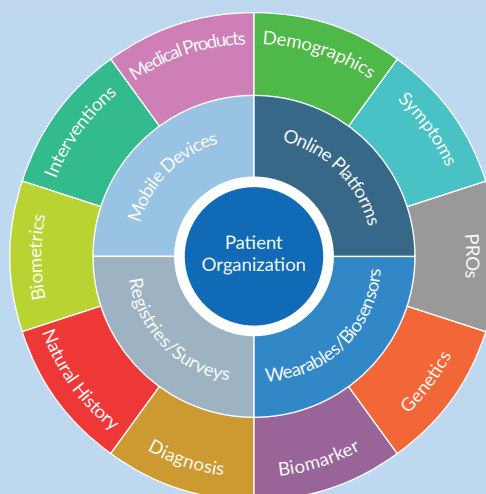
PGHD includes core data elements such as demographic characteristics, diagnoses, interventions, medical product use, and patient-reported outcomes (PROs) (see Figure 1). New platforms developed and maintained by patient organizations and their technology company partners enable monthly, weekly, or even daily data entry by patients at times and in locations that are easiest for each person. Recognizing the increased importance of genetics and proteomics to scientific innovation, patient organizations, such as the National Psoriasis Foundation, also fund or keep biobanks and repositories of genetic data, enabling them to easily share the data with a wide range of researchers. Importantly, registries and survey series can generate data on a patient over time to follow the patient's journey.

Although the uptake in the use of technology for health care has been slower than in other sectors,³ some patient organizations are offering platforms that enable patients to track their symptoms and progress and to compare their experiences to others with the same disease through tables and graphics.

Because the types of data collected by patient organizations vary widely, any set of best practices for ensuring that data are valued and used consistently for research requires a clear definition of PGHD. These data are frequently referred to by individual use case (e.g., lab values) or the technology by which the data are gathered (e.g., social media data, sensor data) rather than by any agreed-upon definition of data content.

The types of data range from demographic data, common to all RWD sources, to genetic data, patient attitudes, and social and environmental data elements that may impact patients' health and well-being. eHealth (e.g., patient portals to capture PGHD) and mHealth (e.g., wearable devices and sensors) technologies will continue to expand the opportunities to capture patient data between clinical visits. In addition, continued advances in data science, including natural language processing techniques and other deep learning methods, will continue to enable analysis of the data captured by patient organizations in new ways.

Figure 1: Data Types and Platforms Used by Patient Organizations



Source: Milken Institute.

3. "Healthcare Must Embrace Digital to Win in Consumer Engagement," Forrester Research, Inc., (November 10, 2016).

III. Infrastructure for sharing, aggregating, and analyzing data from a variety of sources is growing.

Near universal agreement seems to exist that aggregating and analyzing shared data will lead to more and better insights if we can address the technical, cultural, and financial challenges. The most common model consists of two (or more) entities partnering to share data between them to answer a specific research question. Many of these collaborations exist, and they are effective at meeting the needs of those specific partnerships. However, as we move toward the ideal of a frictionless global research data-sharing ecosystem, this model is simply not scalable.

Data repositories to enable sharing have become common, if currently underutilized, in academic science.⁴ For clinical trials, several platforms have emerged in recent years for data sharing and analysis (e.g., Project Data Sphere, the Yale Open Data Access project, Clinical Study Data Request, Vivli), which are beginning to produce valuable insights.

More recently, federated or distributed networks of research and care institutions have been built—including PCORnet, the National Patient-Centered Clinical Research Network; the National Evaluation System for health Technology (NEST); the Food and Drug Administration's (FDA) Sentinel Initiative; and the Global Alzheimer's Association Interactive Network—to enable research via access to (primarily) electronic health record (EHR) and claims data from millions of patients across the United States. The federated data network model aims to create a data process and shared infrastructure, relying on a common data model and syntax, which can facilitate a broad range of inquiry for a diverse array of

users while leaving the data in the hands of each data partner.

Given their scale and structure, federated data networks aim to make clinical research and the generation of real-world evidence faster, less costly, and more reliable for product development as well as for regulatory and clinical decision-making. For data partners, participating in a network can provide access to other organizations working in the same or related disease areas and can facilitate access to a larger or more diverse set of data.



4. For example, Ann Marie Navar, Michael J. Pencina, Jennifer A. Rymer, Darcy M. Louzao, and Eric D. Peterson, "Use of Open Access Platforms for Clinical Trials Data," *JAMA*, 2016;315(12): 1283-1284.

IV. Patient-generated health data are generally not readily available in the environment of shared data networks—but, ideally, they should be.

Shared data networks, including federated models, are in the early stages of incorporating PGHD into their available data set(s). More broadly, to the extent that PGHD are accessible for research or care improvement in the institutions that compose shared data networks, they tend to be collected and controlled by providers and researchers, gathered infrequently, unavailable to patients in a form that creates value for them, and not always driven by patients' interests and priorities. This needs to change.

As ONC notes, "PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways: Patients, not providers, are primarily responsible for capturing or recording these data. Patients decide how to share or distribute these data to health care providers and others."⁵ Both ONC and FasterCures, as well as other health-care leaders, are calling for a person-centered health data infrastructure rather than a provider- or institution-centered one to enable the collection and sharing of this kind of patient-centered health data.

Ideally, PGHD (as defined above) should be included in all clinical research, including research conducted through shared data networks. As we explore in [Part II](#) of this series, patient organizations with data assets can start to fill this gap by partnering with shared data networks to ensure that PGHD are incorporated into the data sets available for analysis. With the emergence of disease-specific and disease-agnostic data networks and patient organizations determined to advance medical research through real-world evidence, now is the time to review and develop models for productive partnerships among these players.

WHAT WERE THE INPUTS TO THIS REPORT?

- Findings from desktop research on existing patient engagement models and on efforts to integrate real-world data (including PGHD) and evidence into medical research and health care
- Findings from interviews with key opinion leaders from patient organizations, research data networks, and other data-sharing thought leaders
- Answers from an online questionnaire of a select group of patient organizations, conducted by FasterCures (and shared by the Genetic Alliance and National Health Council with their members) in September-October 2018
 - Seventy-eight unique organizations described their organizational characteristics (e.g., size, budget, disease areas, existing policies and practices, research assets, partnering practices) as well as their investments in patient data and how they view the challenges and opportunities of linking data to broader networks and platforms.
- Comments from participants of a half-day workshop discussion, "A Patient-Centered Data Ecosystem to Accelerate Medical Solutions," co-convened in October 2018 by FasterCures and the Duke-Margolis Center for Health Policy. Approximately 40 leaders from across the biomedical R&D and health-care delivery and financing systems identified action items to support a business case for investing in PGHD assets and their integration into the broader data ecosystem.

5. "What are patient-generated health data?", HealthIT.gov, <https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data>.

V. Recommendations

If we all agree that PGHD have value and that patient organizations have value as research and data partners, how do we enable more and better collaboration among these stakeholders, particularly in the context of shared data networks? Our recommendations fall into three categories:

- Improve the capacity of patient organizations and other stakeholders to partner
- Optimize the development and use of patient-generated health data
- Develop a framework for partnership in the context of shared data networks

Improve the capacity of patient organizations and other stakeholders to partner

Although the numbers of organizations that are sophisticated research partners, and of platforms and resources for organizations to learn from their peers, are growing, the need remains for more resources aimed at replicating and scaling these models through capacity-building—by patient organizations to become research ready, by organizations with their own patient communities, and by partners to be ready to engage with patient organizations in mutually beneficial ways. There has been a lot of pushing out of information and resources to patient organizations. Now, we must turn our attention to how we can drive the adoption of good approaches and consolidation of efforts if necessary.

The Patient-Centered Outcomes Research Institute (PCORI) is one potential source of funding for capacity-building among

patient organizations. A nongovernmental organization created by the Affordable Care Act, PCORI's mission focuses on the conduct research into health outcomes that is relevant to patients and their caregivers. As such, PCORI has gone to great lengths to ensure the integration of patient perspectives into its prioritization and decision-making processes. Further, it funded the creation of "People-Powered Research Networks" (PPRNs) to experiment with different models to incorporate patient perspective and PGHD into the research conducted within the More recently, federated or distributed networks of research and care institutions have been built—including PCORnet, the National Evaluation System for health Technology (NEST); the Food and Drug Administration's (FDA) Sentinel Initiative; and the Global Alzheimer's Association Interactive Network—to enable research via access to (primarily) electronic health record (EHR) and claims data from millions of patients across the United States. The PCORnet infrastructure has been spun off into a separate nonprofit to ensure its sustainability, and PCORI—which is due for reauthorization by Congress in 2019—will return to being a funding body rather than an infrastructure provider. With this action, PCORI could apply lessons learned from the PPRNs to build capacity among patient organizations to advance their ability to collect and contribute valuable patient data for research.

Patient organizations themselves are becoming more intentional about training their patient communities to serve as research partners. The Arthritis Foundation has initiated a series of training courses to prepare patients to serve as experts in a variety of research settings. One respondent to our questionnaire noted the creation of a

new coalition, HD-COPE, “to organize patient perspective data and to train people with [Huntington’s disease] and their families to present this data to sponsors and regulators in an effective way.”

NEXT STEPS:

- For patient organizations:
 - Define and articulate their value to potential partners (e.g., where they are on the maturity scale proposed in Part II of this series).
 - Define their guiding principles for partnership and expectations (e.g., what benefits should accrue to patients).
 - Understand the incentives and imperatives of potential partners.
- For researchers:
 - Identify where potential partners are on the maturity scale and set objectives and expectations accordingly (e.g., an organization at an earlier stage of maturity can still be a valuable research and data partner, if partners understand their capabilities and assets and factor them into their plans).
 - Understand the incentives and imperatives of patient organization partners.
- For funders:
 - Fund capacity-building by patient organizations to become research-ready partners.
 - Educate other stakeholders about the benefits of partnering with patient organizations and disseminate best practices in patient engagement.

Optimize the development and use of patient organizations’ patient-generated health data

On October 24, 2018, FasterCures and the Duke Margolis Center for Health Policy convened patient organizations, product developers, payers, providers, IT platform companies, and others to identify the highest value uses of PGHD and the barriers to integrating these data into health-care innovation and delivery research. During this workshop, participants highlighted technical barriers such as data standards, common data models, and interoperability, as well as questions about how to improve the quality of PGHD. The FDA recently released guidance to clarify the criteria by which PGHD will be considered “fit for purpose” for regulatory oversight. All workgroup participants expressed concern about protecting patient privacy and support for increasing patient control over their data. They also observed that use of the generated data will not necessarily correct for the inherent biases that currently exist in clinical trial participation.

A significant (but not widely acknowledged) challenge impacting the linking of disparate types of data is the lack of a business model that encourages such sharing. Data aggregators/platforms, health plans, providers, product developers, and researchers understand that their data resources are valuable assets and—acknowledging the financial investments needed to support data aggregation, infrastructure, and analytics—are interested in monetizing their data in the interest of sustainability, if nothing else.

By virtue of their dual role as trusted resources for patients and sources of insight for innovators, patient organizations could play a critical role in expanding the capacity to collect and deploy these new sources of PGHD.

An increasing number of patient organizations are successfully building their data assets

and analytics capabilities, alone or through partnerships. Still others, particularly organizations with small patient populations or with limited funding, have not entered the data space. Although many agree that data help them better serve their patient populations, they know that building or supporting data assets is a challenging endeavor. Combining their data with that of providers, manufacturers, and payers presents added complexity, but, if executed, can yield great benefits to patients, including the ability to predict who will get sick and when.

NEXT STEPS:

- For patient organizations:
 - Carefully consider the purpose of any data gathering, and whether creating a separate resource is the best option or whether collaborative options exist that fit the purpose and are less resource-intensive.
 - Increase the value of data by moving through the maturity scale.
 - Transparently track and report data quality measures (completeness, accuracy, and timeliness).
 - Make potential partners aware of data resources via publications and presentations. Proactively seek partners for data.
 - Craft funding opportunities around the use and reuse of data resources (e.g., Data Challenges)—don't assume users will pursue these opportunities without incentives.
- For researchers:
 - Proactively seek patient organization partners with data assets.
 - Engage with these organizations to provide insight into the data needs of partners and technical requirements for data integration into your work.

- Consider how sharing and linking their data can provide maximum benefit to patients.
- For funders:
 - Fund infrastructure to enable more high-value data collection and sharing by patient organizations (e.g., “white label” customizable platforms or applications).

Develop a framework for partnership in the context of shared data networks

Shared data networks such as PCORnet and NEST have unique structures, goals, and processes that present distinctive challenges and opportunities to engage patients in the definition and answering of research questions.

Whereas clinical researchers, product developers, and perhaps even regulatory review teams could build long-term relationships with patient organizations and advocates in a small number of discrete therapeutic areas, large-scale research data networks are in many ways more transactional in nature and could answer questions in an almost infinite range of therapeutic areas. They also provide a unique opportunity to institutionalize good patient engagement practices and the use of patient-generated health data across the health research and care landscape, by supporting and demonstrating the value of ongoing patient partnerships.

[Part III](#) of this series features a summary of good patient engagement practices for researchers. How might each of these key recommendations play out in contexts such as these?

Patients as Essential Partners	Patients should occupy a seat at the table as proactive partners, functioning not just as trial subjects or as reviewers asked to react to already-developed materials, but as integral members of research governance structures and decision-making processes at both the network and local levels. Policies and expectations for patient engagement by collaborators should be set at the network level. The network could serve as a resource to collaborators for linking to patient-generated data sets, as well as support building capacity by patient groups to serve as research partners and to collect and share patient data.
Establish Partnerships Early in R&D Process	Given their structure as federations of local clinical research and care institutions, there is a need to strike a balance between partnerships with patient organizations with national or international reach, and the desire and need for engagement and relationships with local patients and advocates. When possible, craft strategic partnerships with patient organizations to support ongoing engagement efforts of network collaborators as well as the creation of valuable patient-generated health data assets. Work with patient organizations to create evidence-based common resources such as a consensus patient journey map. Seek out patient organizations with networks of trained patient advocates to maximize the possibility of connecting locally engaged patients with research institutions.
Define Expectations, Roles, and Responsibilities	At the start of a long-term partnership or short-term engagement, the parties should clearly define the expectations, roles, and responsibilities of all partners, including the data being shared, if any. These should be described in agreements between the parties, for example through a memorandum of understanding (MOU) or simple contract and data use agreement, and, ideally, be co-created by researcher and patient partners and revisited regularly. MOUs, or contracts, should also include each party's pre-specified commitments, how they will handle intellectual property and revenue sharing, how the partnership will protect the commercial and confidential information of each party, and how data privacy and security will be addressed.
Fit-for-Purpose Collaborations	Ideally, all parties will share a sense of purpose, agreed on before the start of an engagement. In addition, aiming to collect patient input that is representative of the target patient population is important, and this might mean engaging with multiple patient groups. Given that patient groups differ with regard to size, resources, expectations, data assets, patient population reach, and experience working with researchers, choosing the appropriate patient partners includes trying to match patient group characteristics to the specific needs of the research program. Conversely, it is important for patient groups to evaluate and define their value to research partners and choose research partners/programs that align with their objectives.
Measure Impact and Report Out	As stakeholders develop standard metrics to measure patient engagement, researchers should consider at the start of a patient partnership how the success of the collaboration will be measured. Both researchers and patient groups should establish feedback systems to gather data throughout the engagement process to measure its impact and mechanisms should be put in place to ensure a continuous feedback loop in which results of research are given back to patients and the public.

In our view, any partnership framework must include the following:

- Capacity-building (e.g., sharing of successful models of patient engagement and use of PGHD among network collaborators as well as patient group partners),
- Benefit to patients (e.g., access to interoperable health data, perhaps via Blue Button, actionable information about their health status and care),
- Compensation to patients and organizations for participation (e.g., PCORI's Compensation Framework), and
- Reciprocity (e.g., work together to find solutions if common data models do not account for key variables for a patient population)

CONTINUE TO [PART II: FOR PATIENT ORGANIZATIONS TO LEARN MORE ABOUT:](#)

- The role that patient organizations are playing as intermediaries for patient perspective and participation in research
- How patient organizations can improve their capacity as research partners
- How patient organizations' data can complement other data sources to capture a fuller patient experience in the "real world"
- The growing importance of shared data networks and the value of incorporating patient-generated health data in their research

READ [PART III: FOR RESEARCHERS TO LEARN MORE ABOUT:](#)

- Key characteristics to understanding patient organizations as research partners
- Resources to help identify patient organization partners
- What types of data patient organizations have and why they have invested
- How to most meaningfully and effectively engage patient organizations as research partners

About the Authors

Kristin Schneeman joined FasterCures in April 2005 as program director, with primary responsibility for its innovation portfolio of projects and activities, focused on best practices in the funding and conduct of medical research and innovative collaborations among players in the research enterprise. She brings to FasterCures decades of experience in public policy, politics, academia, and the media. Schneeman served for three years as a senior adviser and policy director to a gubernatorial candidate in Massachusetts, as a policy aide to a US Congressman, and for four years as the front-line manager and chief-of-staff for a senior adviser to Vice President Al Gore. At Harvard University, she directed research projects on future challenges facing governments, and on complex negotiations in business, politics, and international relations. Schneeman began her career as a producer of documentary films, for which she was the recipient of an Emmy Award in 1990.

Valerie Barton, M.A. is chief data strategy officer at the People-Centered Research Foundation (PCRF), where she works with researchers to integrate claims and registry data into the clinical data assets of PCORnet and leads PCRF's patient engagement activities. During her nearly 15 years as a consultant, she assisted clients by bringing data-informed approaches to their health policy development and business strategies. Ms. Barton worked cross-functionally to build research and data practices from the ground up at both Manatt Health LLP and Avalere Health LLC. Under her leadership, her teams conducted quantitative analytics and economic modeling with observational data for pharmaceutical manufacturers, biotech and medical device firms, provider organizations, and foundations. Ms. Barton has focused on analysis of the Medicare program, payment and delivery innovation, and social determinants of health using Medicare, Medicaid, and commercial claims and publicly-available survey and community-level administrative data sources. In the public sector, Ms. Barton was a health policy analyst with the Centers for Medicare and Medicaid Services. There, she wrote federal Medicare regulations governing post-acute care and hospital outpatient payment systems. Ms. Barton began her career as a federal budget analyst with the Congressional Budget Office, where she modeled the impacts of legislative changes on veterans' health and military personnel programs. Ms. Barton serves as a Senior Advisor to FasterCures and on the board of directors for Micah House, a supportive residence in Washington, DC, for women recovering from substance use disorders.

Brenda Huneycutt is a director at FasterCures, a center of the Milken Institute, where she leads the "Enabling a High-Performing Biomedical Ecosystem" program and directs a project portfolio aimed at creating a system that works better for patients. Her work includes developing a biomedical ecosystem performance scorecard, creating tools to increase the representation of patient perspectives in health care decision-making, and driving transparency in medical product development. Prior to joining FasterCures, Dr. Huneycutt was vice president, regulatory strategy and FDA policy at Avalere Health, advising organizations on topics such as patient engagement in drug development, compassionate use/expanded access to investigational products, regulatory exclusivities, the Food and Drug Administration's orphan drug and expedited programs, and the use of real-world evidence in regulatory decision-making. Dr. Huneycutt has also practiced as a patent lawyer in a large firm working on pharmaceutical litigation, and spent many years as a research scientist, primarily studying cell division and cell cycle control in yeast model systems. Dr. Huneycutt holds a PhD in molecular biology from the University of Colorado at Boulder, a JD from the George Washington University School of Law, and an MPH from the Johns Hopkins University Bloomberg School of Public Health.

Acknowledgments

The authors are grateful for the advice and counsel of the following project advisors:

- Gina Agiostratidou, program director, The Leona M. & Harry B. Helmsley Charitable Trust
- Kathy Hudson, founder, Hudson Works and former CEO, People-Centered Research Foundation
- Rachael Fleurence, executive director, National Evaluation System for health Technology Coordinating Center (NESTcc)
- Todd Sherer, CEO, The Michael J. Fox Foundation for Parkinson's Research
- John Wilbanks, senior fellow, FasterCures, and chief commons officer, Sage Bionetworks



SANTA MONICA | WASHINGTON | NEW YORK | LONDON | ABU DHABI | SINGAPORE