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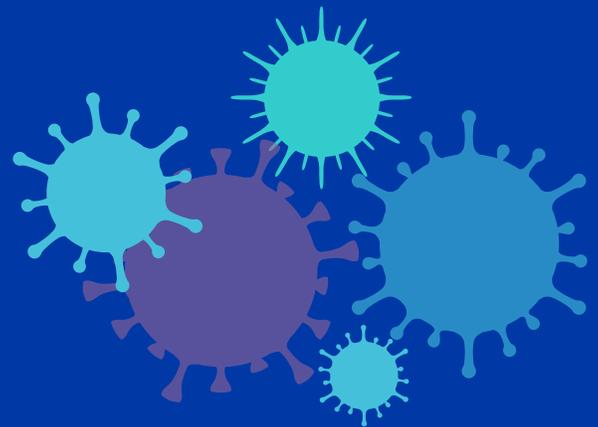
INFRASTRUCTURE, READINESS, AND RESILIENCE

A Long-Term, Biomedical
Systems-Based Response
to COVID-19

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GIVING SMARTER IN THE AGE OF COVID-19

ABOUT US

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 the Center for Strategic Philanthropy

The Milken Institute Center for Strategic Philanthropy advises philanthropists and foundations seeking to develop and implement transformative giving strategies.



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INTRODUCTION

Throughout the COVID-19 crisis, scientists, policymakers, health-care workers, and average citizens worldwide mobilized in ways never seen before to mitigate the challenge at hand. From rapid vaccine development to securing PPE and advocating for precautions to contain the disease, multiple sectors aligned strategies and tactics to lessen the disease’s impacts and financial fallout. Philanthropy has played several crucial roles. The philanthropic response hit an all-time high, exponentially exceeding funding for other recent disasters. For instance, the COVID-19 pandemic solicited approximately 11.9 billion philanthropic dollars within six months; the next closest disaster relief effort, Hurricane Harvey, raised \$400 million in total (“Global COVID-19 Response” 2020).

However, some of this giving, no matter how well-intentioned, has not been as coordinated or effective as hoped. To better prepare for future pandemics, philanthropic capital must be deployed in a coordinated manner that focuses on infrastructure and health systems to address future crises and improve health for all.

As an advisor to family foundations and individual philanthropists, the Milken Institute Center for Strategic

Philanthropy (CSP) fulfills the unique role of ensuring that philanthropic dollars are strategically deployed, maximizing that capital’s impact on a given issue. To develop this guide, CSP worked with FasterCures, another center of the Milken Institute focused on biomedical R&D, to elucidate the accomplishments and setbacks of the COVID-19 pandemic response. CSP interviewed more than 20 experts and stakeholders from the private and public sectors about the systemic shortcomings of the pandemic response to identify opportunities for improvement. FasterCures published a white paper as a result of this effort, titled [“Lessons Learned from COVID-19: Are There Silver Linings for Biomedical Innovation?”](#).

CSP’s research for this report identifies four main areas ripe for greater philanthropic investment: (1) Accelerating Product Development; (2) Clinical Trial Design and Execution; (3) Research Collaboration; and (4) Racial and Ethnic Disparities in Health-Care and Medicine.

Stakeholders interviewed for this report highlighted how the pandemic brought long-observed weaknesses in our health infrastructure to a breaking point. These weaknesses forced health-care workers, researchers, and civil servants to create ad hoc workarounds during the most frenzied

FIGURE 1: PHILANTHROPIC FUNDING FOR COVID-19 COMPARED WITH RECENT DISASTERS

COVID-19	\$11,914,055,871
Hurricane Harvey	\$342,771,699
Australian Bushfires	\$152,377,848
Hurricane Irma	\$127,309,374
Hurricane Maria	\$68,105,408
Hurricane Dorian	\$47,741,000

Note: Based on data, in US dollars, collected for roughly six months following each disaster. Source: Candid and Center for Disaster Philanthropy (2020)

moments of the crisis. Even as federal agencies, the pharmaceutical industry, and academic researchers kicked into overdrive to combat the challenges of the pandemic, the cross-sector connection necessary for making true strides and achieving lasting change was notably absent. In our research, a clear theme emerged: Philanthropy can drive coordinated action in times of chaos, connecting people, ideas, organizations, and systems.

Perhaps more important for the future, philanthropy can help preserve the successful processes that emerged during this pandemic, documenting the lessons that will inform a system that can be immediately activated when a similar situation arises. In this way, philanthropy can help to proactively build a resilient infrastructure that ensures our preparedness to handle future pandemics and increases the efficiency of non-pandemic R&D. CSP has identified eight opportunities for philanthropy to influence collaboration, community, communication, and coordination across the key domains of pandemic response.

AREA OF INVESTMENT	PHILANTHROPIC OPPORTUNITY
Accelerating Product Development	<p>Philanthropic Opportunity 1: Invest in Cross-Cutting Platform Technologies</p> <hr/> <p>Philanthropic Opportunity 2: Prepare the Downstream Systems: Manufacturing and Distribution</p> <hr/> <p>Philanthropic Opportunity 3: Partner with Expert Scientific Communicators to Collate and Disseminate Vetted Information</p>
Clinical Trial Design and Execution	<p>Philanthropic Opportunity 4: Lay the Groundwork for Clinical Trial Coordination</p> <hr/> <p>Philanthropic Opportunity 5: Recruit the Public</p>
Research Collaboration	<p>Philanthropic Opportunity 6: Democratize Knowledge through Integrated Data Platforms</p> <hr/> <p>Philanthropic Opportunity 7: Scientific Storytelling</p>
Racial and Ethnic Disparities in Health-Care Research	<p>Philanthropic Opportunity 8: Connect Health-Care and Research Opportunities to Communities</p>



ACCELERATING PRODUCT DEVELOPMENT

To respond effectively to a public health crisis, the development of products to treat or prevent the emerging pathogenic threat is crucial. The diversity of medical products required to address the COVID-19 crisis, including testing assays, diagnostic technologies, novel therapeutics, repurposed drugs, and vaccine candidates, has presented a unique challenge because large teams are needed to tackle these complex development processes simultaneously.

The vaccine enterprise provides a key example of successful pandemic-driven product development. Manufacturers were able to accelerate the development of new vaccines because of prior investment in platform technologies (“The Story of MRNA” 2020). Platform technology builds upon an existing framework and uses information specific to the current virus to customize a solution.

Therefore, companies such as Moderna were able to deploy their systems to accelerate the typical vaccine development timeline. In addition, the vaccine enterprise participated in extensive data sharing, collaborative networks, and crosstalk. Finally, the pandemic’s urgency caused vaccine developers to prioritize clinical trial enrollment, ensuring rapid data generation and collection. This approach was in stark contrast to the typical challenges and financial barriers of vaccine development. As a result, the COVID-19 vaccine trials were efficient, adequately powered, and accelerated to achieve efficacious vaccines.

PLATFORM TECHNOLOGY:
a curated group of technologies that serves as an infrastructural foundation upon which varying applications may be developed and/or implemented

However, the development of medical products experienced some hiccups. For example, testing within the United States was uncoordinated, inaccessible, and often inaccurate. Out of necessity, therapeutics were developed without basic mechanistic understanding of the virus, which led to inconclusive development processes and trials. Finally, even though the initial development of these products is complete, many challenges are expected to be embedded in the manufacturing and distribution processes.

Philanthropists can learn from the successes and setbacks in product development to improve our response to future pandemics. If anything is clear, it is that infrastructural and systematic investments in the development pipeline will better prepare pharmaceutical companies, health-care systems, and patient communities for a swift, resilient, and scientifically informed response in the product development arena.

Philanthropic Opportunity 1: Invest in Cross-Cutting Platform Technologies

Many experts outlined the crucial role of platform technology in the vaccine space. Platform technologies are the foundational scientific infrastructure upon which interchangeable applications are developed. They allow for completion of most of the development work before an emergency situation occurs; virus-specific information is then applied to the platform when a disease threat becomes imminent, allowing science to move swiftly and nimbly. Beyond vaccines, similar concepts can be applied to diagnostic and serological testing, which is essential for tracking disease spread and stopping transmission.

Intentional philanthropic investment in platform technologies can contribute to a pandemic-proof future. The goal would be to develop a disease-agnostic system that can be applied to diagnostics, treatment, and prevention, thereby improving preparedness. Looking toward diagnostic platforms, this type of technology could be distributed to health-care facilities so that medical providers can activate the system in a testing capacity when a pandemic occurs.

Philanthropic Opportunity 2: Prepare Downstream Systems: Manufacturing and Distribution

Thus far, the government and private sector have funneled an immense amount of capital into vaccine and therapeutic development in response to COVID-19. Many experts have voiced concern that manufacturing and distribution pipelines lack the resources, coordination, and efficiency necessary to develop vaccines and therapeutics on such a large scale. Philanthropy can be the objective, apolitical intermediary to help address supply chain demands and vaccine distribution.

Targeted philanthropy can help to scale up manufacturing infrastructure in advance of a finalized product, especially for smaller companies without the means to do so themselves. Investment in the effective distribution of a therapeutic or vaccine, both domestically and globally, would be highly beneficial. Such an investment could take many forms, from reserving manufacturing slots in advance to create promising drugs to coordinating the distribution of supplies to companies that need them.

Philanthropic Opportunity 3: Partner with Expert Scientific Communicators to Collate and Disseminate Vetted Information

The science and statistics needed to navigate information during a pandemic are complex and difficult for the general public to grasp. However, increasing fundamental understanding of scientific concepts, such as vaccine development processes, the accuracy of types of diagnostics, repurposed compounds, and the course of the disease would greatly improve the public's ability to interpret rapid scientific advances and evaluate trusted sources. Whether in the form of a resource library or public knowledge coursework, the collation of scientific educational resources and instruction could deliver knowledge and comfort to the general public during a scary and uncertain time.

CLINICAL TRIAL DESIGN AND EXECUTION

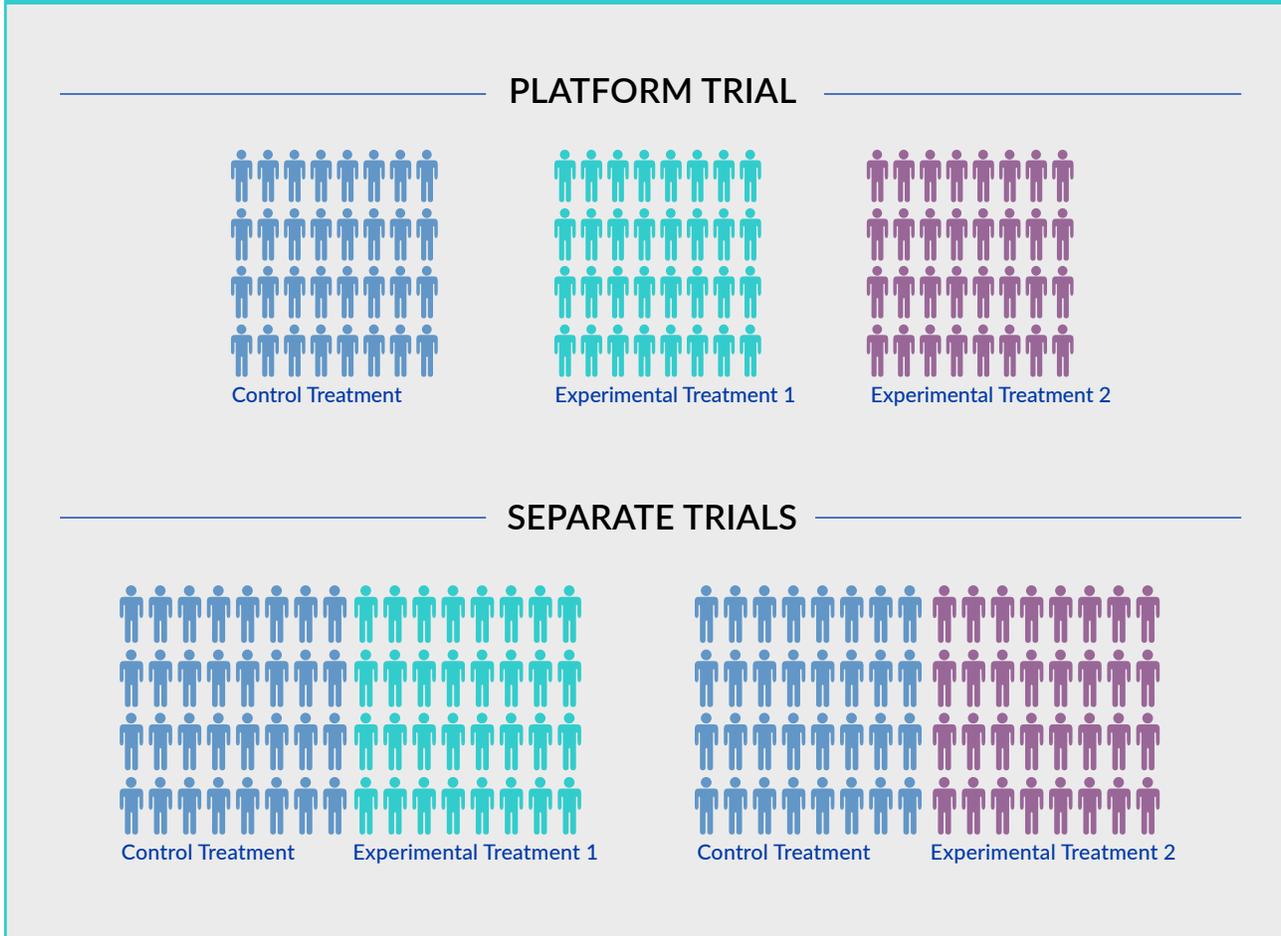
The COVID-19 pandemic caused an immediate surge in therapeutic and vaccine research and, as a result, increased the number of clinical trials for treatments and vaccines. Occurring in the midst of a massive global shutdown, this increase presented additional challenges for investigators, which led to innovation in clinical trial design and implementation. Experts agree that longstanding efforts to connect communities to the research ecosystem have been accelerated due to the remote nature of life during the pandemic. Researchers and society have adopted and embraced decentralized clinical trials, home monitoring, and telemedicine. The performance of remote patient visits and monitoring and deployment of nurses to specific patients are two practical applications likely to continue. Additional philanthropic support can further improve clinical trial coordination and participation.

Philanthropic Opportunity 4: Lay the Groundwork for Clinical Trial Coordination

Many trials for COVID-19 therapies and vaccines launched quickly, and they required many participants. However, too many simultaneous trials can lead to underpowered studies and uninterpretable results. Fortunately, this problem is solvable through a mechanism of shared trials, known as a platform trial. These trials share protocols and placebo groups but can test multiple treatments from different manufacturers simultaneously. Philanthropic investment is primed to lead this endeavor and to ensure the necessary collaboration among clinicians and therapeutics developers.

Platform trials with master protocols and shared placebo groups are becoming recognized as a more efficient mechanism for performing clinical trials. Master protocols allow for a streamlined standard of care, and shared placebo groups decrease the number of patients needed for each trial, as well as the number of patients who do not receive a therapeutic. Because master protocols require higher stakeholder involvement and investment, they tend to be implemented in a way that satisfies regulators' data requirements. Expanding this model into other disease areas beyond COVID-19 could enable the completion of more trials and ensure its broad acceptance and ready deployment in a future public health emergency. A neutral coordinating body to identify and prioritize trials, ensuring that they are well powered and yield actionable results, will be crucial to continue progress in this area.

FIGURE 2: PLATFORM TRIALS FEATURE SHARED CONTROL GROUP ACROSS STUDIES



Source: Illustration of platform trial featuring shared control group. Adapted from James M. S. Wason, Lynne Stecher, and Adrian P. Mander, "Correcting for Multiple-Testing in Multi-Arm Trials: Is It Necessary and Is It Done?," *Trials* 15, no. 1 (September 17, 2014): 364, <https://doi.org/10.1186/1745-6215-15-364>.

Philanthropic Opportunity 5: Recruit the Public

A critical asset in clinical trial execution is the individual philanthropist's voice, which adds personal experience to the public conversation to drive substantive change. This asset can play a key role in broadening the recruitment of participants in randomized control trials (RCTs), which are necessary to understand which therapies are most beneficial in medical care. Minorities have been disproportionately affected by COVID-19, and their participation in RCTs is important to validate the effectiveness of the vaccine or treatment in the groups most in need. Philanthropy has a unique opportunity to educate the public and produce messaging that emphasizes the importance of participation in clinical trials and communicates realistic trial timelines and outputs. This effort requires building trust and a presence in the communities from which the RCTs must recruit. Philanthropy can bolster collaboration with community leaders and groups—thereby playing a transformative role in clinical trial recruitment and public support of vaccines and therapeutics.

RESEARCH COLLABORATION

With its myriad of symptoms and potential disease courses, the SARS-CoV-2 virus has highlighted the importance of patient focus and rapid therapeutic development in disease research. Traditionally, the research ecosystem is siloed, which can result in misaligned research goals. Keeping patient care goals and rapid development at the forefront means that systems built for collaboration and data sharing must be made available and put to use by researchers and clinicians. Philanthropy is poised to bolster these efforts by supporting data-sharing platforms. This support allows scientists to navigate their research with fewer roadblocks, and this seamless sharing of knowledge is particularly important during public health emergencies.

Philanthropic Opportunity 6: Democratize Knowledge through Integrated Data Platforms

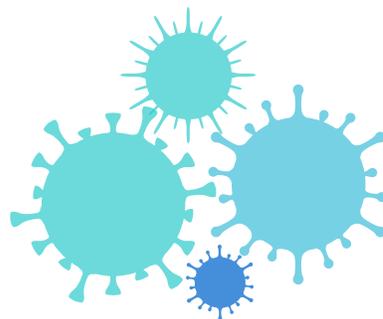
There has been a distinct call for platforms where scientists and clinicians can engage with one another and verify accurate and efficient data integration. Generally, data collection is also siloed. Philanthropy can be applied to designing a data platform, an “information commons,” that allows scientists to share data with ease, actively encouraging collaboration. An example of this type of commons is the UK Biobank, which contains the genetic and health information of more than 500,000 UK citizens. This data commons provides researchers with access to large, streamlined datasets to conduct research more efficiently and on a larger scale (“UK Biobank” n.d.).

Health-care systems could also benefit from a data platform that enables rapid collection of patient data and analysis of the natural course of a disease. These advantages will be essential to future pandemic responses because the scientific community can understand the pathogenesis of the virus in real time and then use this existing evidence to develop therapies and vaccines. In addition, the collection, curation, and dissemination of these natural history data via publicly available systems would inform scientists’ understanding of the epidemiology of a given virus. If in place before a public health crisis, this coordinated research platform and infrastructure would normalize the practice of health monitoring and provide improved baseline data to create systems that are more reactive.

Finally, this concept can be applied to repurposed drugs, which can be a key component to pandemic response. These compounds have been developed for other indications and have proven safety and efficacy. Early in the COVID-19 pandemic, the pharmaceutical community tried to repurpose as many existing drugs as possible, triggering a chaotic process of evaluation and regulatory processes to use existing drugs to combat the novel coronavirus. By leading the development of a pandemic-ready platform that indexes existing drugs and their mechanisms of action, philanthropy could help ensure preparedness for future public health crises.

Philanthropic Opportunity 7: Scientific Storytelling

Experts noted a major gap in communication and storytelling pertaining to the scientific processes and players involved in the COVID-19 response. Philanthropists could partner with industry and/or government to perform the communications work that these stakeholders are not in a position to prioritize. For example, philanthropy could foster an effort to tell stories of innovation, teamwork, and real-world science in action to illustrate the impact of COVID-19. This effort would humanize the herculean effort underway and improve the public's engagement with and understanding of science over the long term.



RACIAL AND ETHNIC DISPARITIES IN HEALTH-CARE RESEARCH

In 2019, the Food and Drug Administration (FDA) created a Minorities in Clinical Trials initiative and issued guidance on collecting race and ethnicity data in clinical trials ("Enhancing the Diversity of Clinical Trial Populations" 2020). However, FDA lacks the authority to mandate policies for diversity and inclusion in clinical trials. The pharmaceutical industry is making strides to require diversity in clinical trials. For example, Eli Lilly requires trials with more than 25 sites to have at least 2 sites with non-White representation of at least 25 percent ("As Women and Minorities Seek Equality" n.d.), and it has deployed mobile units to facilitate trial participation. Although these first steps are promising, additional connections between industry and community organizations are needed to foster more trust and understanding, specifically about minority groups' reasons for not participating in trials. Experts believe that the involvement of more researchers and physicians who serve communities of color is needed to bridge the communication gap and foster trust between the research community and minorities. In the absence of government policies or mandates, change in this arena will not come quickly; it will take hard work and sustained effort. Philanthropy is poised to be the voice that communicates the necessity—and worth—of this hard work.

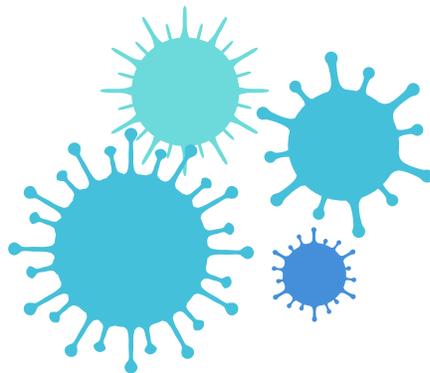
Philanthropic Opportunity 8: Connect Health-Care and Research Opportunities to Communities

Systemic racism and inequities in health-care provisions have led to deep-seated institutional distrust and fear of the health-care system among minority groups. As a result of this and other social determinants of health, these groups typically have higher rates of comorbidities and poor disease outcomes.

COVID-19 has illustrated even more nuanced disparities in health care, showing how socioeconomic standing can increase illness risk. Black, Latinx, and Native American people are disproportionately required to perform in-person work, which likely contributes to their higher rates of COVID-19 infection and mortality (Zelner et al. 2020). This toll has emphasized the need to expand investment in workplace safety beyond access to PPE to include guidelines for best practices and a forum to share and communicate information. As stated above, the participation of minority groups in RCTs is necessary to validate the effectiveness of the vaccine or treatment in the groups most in need. Research has shown that it takes more time and resources to recruit elderly and minority patients for trials, and industry realizes the need to think outside of the box to find solutions to this problem (Gul & Ali 2010). As a part of the solution, industry must build a presence in the communities from which RCTs must recruit, and philanthropy can bolster collaboration with community leaders and groups to form thoughtful, relationship-centered approaches to community engagement.

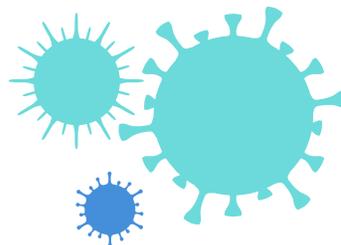
CONCLUSION

Global health is a complex field, and its navigation in the context of a novel disease is exponentially more challenging. During the COVID-19 pandemic, researchers, health-care workers, and civil servants worldwide have risen to the occasion—developing, manufacturing, and distributing virus and antigen tests, as well as therapies and vaccines, in record-breaking time. These achievements did not come without challenges, and experts have identified ways that the pandemic has created opportunities for resilience and innovation. Philanthropy has been identified as the group especially well-positioned to bring together organizations, ideas, and systems to focus on collaboration, communication, and community. Although this role can seem daunting, especially for people new to philanthropic endeavors, participation and leadership can create lasting change. The legacy effect will be resilient systems that provide more equitable and effective public health-care for all.



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