MILKEN INSTITUTE
FasterCures

LESSONS LEARNED FROM COVID-19:

ARE THERE SILVER LININGS FOR BIOMEDICAL INNOVATION?

Executive summary of a FasterCures white paper, coming January 2021

As the COVID-19 crisis has unfolded, policymakers, scientists, and companies have jumped into the fray to develop the tools needed to rapidly combat the virus. We have seen many fault lines exposed that FasterCures has identified as slowing progress in biomedical R&D even in the best of times. We have also seen remarkable innovation in the R&D process born of necessity. FasterCures wants to ensure that the lessons of this crisis are not lost when the current urgency subsides—for not only combatting future infectious disease outbreaks but also conducting every other kind of biomedical R&D.

Through research and three dozen interviews with key opinion leaders from government, industry, academia, and the nonprofit sector, we have identified promising policies and practices that have emerged from the COVID-19 crisis to be preserved and improved on and begun to explore what needs to happen to realize those opportunities.

Key Takeaways and Opportunities for Future Focus

- **Research Collaboration.** While it has often lacked coordination and has sometimes been more talk than action, there has been an unprecedented scale and speed of collaboration among researchers, companies, and government entities—domestically and internationally—to tackle the challenges the novel coronavirus presented.

1. Repurpose infrastructure that has been created, such as the National Institutes of Health's ACTIV and RADx initiatives, and target it at other high-priority, unmet health needs. Dovetail with existing public-private partnerships to amplify impact.
2. Formalize efforts that are working, such as the Reagan-Udall Foundation's Evidence Accelerator, and provide incentives for their use.
3. Initiate a public dialogue about the future of scientific communication, specifically the nexus of peer-reviewed journals and pre-print servers.
4. Document, characterize, and, to the extent possible, quantify the benefits of collaboration during COVID-19.

- **Acceleration of Product Development.** Faster R&D timelines are largely due to an extraordinary investment of financial and human capital, but they are also the result of long-term investments in platform technologies and infrastructure, the deployment of innovative research designs and approaches, and regulators' speed and flexibility.

5. Invest in platform technologies (such as mRNA and prototype pathogens) and research infrastructure that can benefit many researchers and developers.
6. Capture and share efficiencies in trial design and conduct during COVID-19, such as master protocols, seamless trials, and pragmatic trials. Update Food and Drug Administration (FDA) guidance as needed to give sponsors confidence to use these approaches after the pandemic.
7. Initiate a public dialogue about agile regulation, considering how it might be more flexible and adaptive based on need. Support FDA efforts to make guidance more rapid and iterative.
8. Consider how user fee negotiations and 21st Century Cures 2.0 legislation can provide support and authorization for priorities emerging from the pandemic experience.

- **Clinical Trial Design and Execution.** Innovations such as master protocols, platform trials, and adaptive designs have shown their value in bringing speed and efficiency to the trial process. The use of remote tools and decentralized approaches to keep non-COVID trials going has also taken off during the pandemic.

9. Keep COVID-19 trial infrastructure, including platform trials and networks such as the COVID-19 Prevention Trials Network, in place to streamline and incentivize research in areas of high unmet need.
10. Make more efficient and effective trial models, such as master protocols and seamless trials, the norm rather than the exception through public and private funding, incentives and policies, and regulatory guidance.
11. Support, expand, and link clinical trial networks. Develop a more pragmatic trial network to reach more participants through community-based settings and run larger, simpler trials.
12. Invest in making decentralized trials and use of remote tools easier to adopt.

- **Collection and Use of Real-World Data and Evidence.** There has been real progress made in integrating real-world data (RWD) from disparate sources in centralized platforms to enable faster learning, deploying it to drive hypotheses and improve care, and demonstrating the value of randomized real-world evidence (RWE) as a rapid, rigorous knowledge-generation engine.

13. Sustain valuable RWD/RWE platforms and initiatives like the Evidence Accelerator and National COVID Cohort Collaborative (N3C) and deploy them against other urgent public health questions.
14. Invest in pragmatic trials networks for rapidly generating real-world data and evidence.
15. Integrate lessons learned into FDA's existing plans, frameworks, and guidances on RWE and technology modernization.

- **Racial and Ethnic Disparities in Health Care and Research.** COVID-19 has elevated longstanding health inequities to public consciousness to an extent not seen before. Attention is not sufficient, but it is a critical prerequisite to action, and we must seize this moment to make real change.

16. Build relationships and trust with individuals and partner organizations in minority communities.
17. Bring leadership, resources, and cohesive plans to set priorities and create accountability across stakeholders.
18. Improve data collection and use.
19. Broaden eligibility criteria and change study designs to include more participants.
20. Bring trials to the communities you need to engage through site selection and building more robust trial networks as well as use of remote tools.