MILKEN INSTITUTE

PROTECTING THE PROGRESS FOR BIOMEDICAL INNOVATION: A POST-PANDEMIC SCORECARD

EXECUTIVE SUMMARY

> ***"The further out we go, the harder we'll be graded, the harsher we'll be judged, I'm afraid … But I think we did learn a lot."—Interviewee***

In the midst of the COVID-19 pandemic in 2020, FasterCures set about capturing lessons learned and key takeaways and opportunities for the medical research ecosystem. The resulting report, *Lessons Learned from COVID-19: Are There Silver Linings for Biomedical Innovation?*, offered recommendations for retaining those pandemic-era lessons and innovations for other health conditions to policymakers and other leaders. Since the release of that paper, FasterCures has produced an *Implementation Roadmap* and continued to work directly on some of the recommendations from the report.

With the public health emergency (PHE) officially ending in 2023, we developed a "scorecard" to assess the country's current performance regarding those recommendations, which centered on five broad areas: (1) research collaboration, (2) acceleration of product development, (3) clinical trial design and execution, (4) collection and use of real-world data and evidence, and (5) addressing racial and ethnic disparities in health care and research. **Our objective with this scorecard is to keep these issues front and center with the biomedical innovation ecosystem—highlighting positive progress and areas requiring additional focus and resources.**

By necessity, this exercise is subjective. It has been less than three years since the report's release, and its recommendations were wide-ranging and long-term. We sought discrete indicators of continued focus on and commitment to our recommendations rather than broad evidence of quantifiable outcomes. In addition to desktop research, we re-interviewed many leaders we spoke with in 2020.

We uncovered a surprising number of positive developments across the five domains. In part, that may be because many of the most successful pandemic response initiatives were built on the bones of preexisting efforts and were given a jolt of energy by the emergency. We heard loud and clear, however, about a number of significant impediments.

- Although the level of financial and human **resources** deployed could not continue after the pandemic, enhanced public and private capital are needed but are constrained by political and market factors.

- Building and maintaining critical **infrastructure** for more efficient clinical research is an expensive and long-term proposition, although the pandemic clearly demonstrated its value.
- Pandemic response requires coordinated **leadership** but so does the "peacetime" clinical research enterprise, and it seems we are no closer to achieving that.

A number of issues that had not come to the fore when we issued our 2021 report were cited as causes for concern by the key opinion leaders we interviewed this year. The level of mistrust in science and health leadership, as well as mis- and disinformation, has grown to significant levels. Geopolitical tensions are creating a chilling effect on international scientific collaboration.

Although urgent unmet health needs and significant impediments to collaboration and acceleration remain, the biomedical innovation ecosystem seems to have taken to heart some of the lessons learned in the crucible of COVID-19 and is striving to institutionalize them.

> ***"Here we are in a country seeing the biggest decline in life expectancy in our history, and it's not just COVID. I would say the alignment between all the sectors and what needs to be done specifically about what's causing the death and disability in our country is not very good right now."—Interviewee***

	**Research Collaboration** Although we are seeing a continued natural desire for stakeholders to work together, we see little focus on addressing incentive systems, funding, infrastructure, and governance challenges necessary to build and sustain collaborative ventures.	C+
	**Acceleration of Product Development** In the near term, investment in platform technologies has continued, along with legislative and regulatory action, to capture and implement lessons learned from the pandemic experience, although the outcomes will take some time to manifest.	B
	**Clinical Trial Design and Execution** Although much of the clinical trials infrastructure put in place for the pandemic has not been maintained, there is evidence of sustained awareness of and interest in improving trial design and building inclusive networks by both the public and private sectors.	B-
	**Collection and Use of Real-World Data and Evidence** Improvement in the use of real-world data/real-world evidence (RWD/RWE) for product development and evaluation continues its pre-pandemic momentum, although attention is needed to the infrastructure required for such research.	B-
	**Addressing Racial and Ethnic Disparities in Health Care and Research** Much work remains to be done, but commitment and resources are being sustained in the near term, with some early progress in evidence.	C+
OVERALL GRADE: B-		