MILKEN INSTITUTE

Protecting the Progress for Biomedical Innovation: *A Post-Pandemic Scorecard*

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ABOUT THE MILKEN INSTITUTE

The Milken Institute is a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life. With a focus on financial, physical, mental, and environmental health, we bring together the best ideas and innovative resourcing to develop blueprints for tackling some of our most critical global issues through the lens of what's pressing now and what's coming next.

ABOUT FASTERCURES

The Milken Institute's FasterCures 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.

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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 (see Acknowledgments).

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-	

C+

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.

> **"Researchers are more ready to collaborate, but the funding necessary to create the environment to foster that in the long term, I'm not quite sure it's working properly."—Interviewee**

One of the most striking aspects of the COVID-19 experience was the way in which everyone, inside and, in many cases, outside of the biomedical innovation ecosystem, instinctively set aside competitive drivers, aversion to risk, and incentives that often subconsciously underlie their actions to work together for collective benefit. Everyone wanted to contribute whatever they could to solutions. It gave the lie to the adage, "If you want to go fast, go alone. If you want to go far, go together." In this instance, we went fast together.

In the wake of the pandemic, that natural desire to work in partnership has not disappeared, but we are not using the platforms that were created or leveraged during the pandemic to support continued collaboration. As one might expect, much effort has been devoted to rethinking (again) how to organize national and global coordination in the face of a PHE. However, little to no effort has occurred to put this infrastructure to work to address other urgent unmet public health needs—if only to keep it "warm" between crises.

As the resources poured into the pandemic response ebb, discussion about funding collaboration platforms with public, philanthropic, or private money has been limited in the US; focus and commitment are greater in places outside the US, such as Canada, the EU, and Australia. Geopolitical tensions are challenging global research collaboration. Knowledge sharing, which is critical to collaboration and was rapid and iterative during the pandemic, is returning to its pre-pandemic state—in the academic journal publishing industry, at least, which is pushing back on the Biden Administration's efforts to make results of federally funded research more widely available. The academic incentive system that can dissuade collaboration and data sharing largely remains in place.

In some instances, pandemic platforms are being directed at other purposes. For example, the Veterans Affairs (VA) research enterprise, always an under-appreciated national resource, is undergoing a pandemic-inspired transformation and is directing its energies at oncology as a pilot. Some of our interviewees appreciated the subtle ways in which the COVID-19 experience built relationships and trust that persist within and across sectors and international

boundaries. Industry R&D leaders are more willing to come together in a precompetitive way to answer challenging questions, for instance, and new pathways for international regulatory communication are emerging. “I don’t think we can really unlearn it,” one interviewee noted of the experience of collective problem-solving. Ultimately, however, we need not only the will but also the ways to collaborate, which necessitate sustained funding, new incentive models, leadership, and coordination at the highest levels.

Repurpose the infrastructure that has been created to target other high-priority, unmet health needs. Dovetail these efforts with existing public-private partnerships to amplify impact.	The ACTIV trials platform and National COVID Cohort Collaborative (N3C) still exist but have not been directed at other health needs.	
	ACTIV’s Clinical Trial Capacity Inventory has not been maintained, although training resources have been made available.	
	RADx remains active and has been directed to other health needs, such as hepatitis C and maternal health.	
	The Reagan-Udall Foundation Evidence Accelerator model is being applied to improve the standard of collection and curation of race and ethnicity data.	
Formalize and provide incentives to use efforts that are working, such as the Reagan-Udall Foundation’s Evidence Accelerator.	As a result of its pandemic experience, VA Research has embarked on an Enterprise Transformation and is piloting its efforts in oncology.	
	The RECOVER initiative to address long COVID employs some of the methods of the COVID response but has been slow to activate and has spent its funds on observational research rather than treatment.	
	The INTREPID Alliance provides an industry-led forum for public-private sector collaboration on development of antivirals.	
	International regulatory collaboration continues through efforts such as the expansion of the European Medicines Agency’s OPEN framework to non-COVID products.	
Initiate a public dialogue about the future of scientific communication, specifically the nexus of peer-reviewed journals and preprint servers.	The White House issued guidance to make the results of taxpayer-supported research immediately available to the public at no cost, though Congressional action could block it.	
	Use of the bioRxiv preprint server continues to be high, with monthly submissions rivaling the peak of the pandemic.	
	cOAlition S has ended financial support for subscription journals to transition to full and immediate open access due to lack of progress.	
Document, characterize, and, to the extent possible, quantify the benefits of collaboration during COVID-19.	US government leaders and the United Nations, among others, have documented lessons learned from the pandemic, specifically around collaboration and coordination.	
	Congress has not formed an independent commission to evaluate the US COVID response.	
OVERALL GRADE: C+		

“We have to think of these platforms essentially as infrastructure. … The car won’t start if you haven’t kept it running in between times.”—Interviewee

B

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.

> **"For clinical trials, it's the best of all times and the worst of all times. We have the technologies, we have the techniques, but there's still a lot of conservatism. And if the regulators don't lead the way, the industry is not going to push because all they want is predictability."—Interviewee**

Faster R&D timelines during the pandemic were due to not only an extraordinary investment of financial and human capital but also long-term investments in platform technologies and infrastructure, deployment of innovative research designs and approaches, and regulators' speed and flexibility. The 24/7 nature of the response could not be replicated outside of a PHE, and processes such as the Emergency Use Authorization are largely unavailable in nonemergency settings. However, some of the ways in which the evaluation process was conducted to minimize timelines without sacrificing patient safety offered important lessons.

The good news is that the Biden Administration and Congress seem to have learned some of those lessons and are taking action to preserve them. New resources are being invested in platform technologies, particularly—though not only—those relevant in a pandemic. Research infrastructure has been explicitly identified as a priority, even a national security asset. However, investment in infrastructure is a large, long-term, and diffuse proposition, so evidence of progress is more difficult to come by.

At the global level, although large, international commitments such as the G7's 100 Days Mission have not yet resulted in significant action or new resources, individual countries are placing higher priority on building their national clinical research capacity and infrastructure. Canada's pandemic-inspired Biomanufacturing and Life Sciences Strategy, for instance, created a new Clinical Trials Fund and Consortium.

In the US, a flurry of legislative activity at the end of 2022, which included the Food and Drug Omnibus Reform Act (FDORA) and the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), captured a significant number of lessons learned from the pandemic and created pathways for preserving them. The Food and Drug Administration (FDA) has also initiated several new efforts to make regulation more flexible and adaptive.

Whether these efforts ultimately make sponsors more willing to accept the additional risks and uncertainty of working in new ways and result in accelerated product development remains to be seen. In addition, resource constraints and political pressures are causing global regulators

to retreat to more conservative positions, particularly at the reviewer level, even as leadership expresses support for flexibility, collaboration, and innovative approaches.

Invest in platform technologies, such as mRNA and prototype pathogens, and research infrastructure that can benefit many researchers and developers.	Project NextGen is deploying $5 billion to support next-generation medical countermeasures. The National Institute of Allergy and Infectious Diseases created the $100 million ReVAMPP Network for R&D on prototype pathogens.	
	The Advanced Research Projects Agency for Health is developing mRNA platforms to treat a range of diseases, as well as infrastructure to bring cancer trials to diverse communities. Industry is pouring billions of dollars into mRNA vaccines for noncommunicable diseases.	
	The National Biodefense Strategy and American Pandemic Preparedness Plan identify research infrastructure as a priority.	
	The G7's 100 Days Mission seems to have made little headway or investment.	
Capture and share the efficiencies of COVID-19 trial design and conduct. Update FDA guidance to give sponsors confidence.	FDA, the Clinical Trials Transformation Initiative (CTTI), and the ACTIV team captured and shared lessons learned from COVID trial conduct.	
	The International Council for Harmonisation (ICH) is rapidly updating guidance on good clinical practice, and the World Health Organization (WHO) is drafting guidance on it as well.	
	FDA's oncology center launched Project Pragmatica to explore the use of real-world design elements in cancer trials.	
Initiate a public dialogue about how regulation can become more agile based on need. Support FDA efforts to make guidance more rapid and iterative.	FDA leadership outlined an approach to an adaptive policymaking structure and agile regulatory system.	
	FDA has initiated several programs to pilot more flexible, frequent communication with sponsors, including the Total Product Life Cycle Advisory Program (TAP) and "Operation Warp Speed for rare diseases."	
	The new Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Program complements expedited evaluation pathways with a similar approach to CMC.	
Consider how user fee negotiations and 21st Century Cures 2.0 legislation can provide support and authorization for priorities that are emerging from the pandemic experience.	FDORA requires FDA to issue or revise guidances on decentralized trials, digital health technologies, and seamless, concurrent, and other innovative designs.	
	FDORA created a new Type D meeting for faster communication with sponsors.	
	FDORA created a designation for Advanced Manufacturing Technologies, and PREVENT Pandemics created a designation for Platform Technologies.	
	21st Century Cures 2.0 is stalled, but that is because many of its priorities were included in the 2022 omnibus spending bill.	
OVERALL GRADE: B		

"That [regulatory pilot] is part of a lesson learned from COVID. And that's incredibly exciting, because it truly is for innovators, about reducing the time and cost of the Valley of Death, making that more predictable."—Interviewee

B-

CLINICAL TRIAL DESIGN AND EXECUTION

While 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.

> "There's nobody in charge of the clinical evidence generation system."—Interviewee

The clinical trials enterprise is vast, heterogeneous, and complex, particularly in the US, and it does not touch the vast majority of people who need to be engaged. Despite many efforts over decades to spotlight and address these shortcomings, little has fundamentally changed in terms of timelines, cost, or representativeness. During the pandemic, however, we saw how quickly and efficiently the enterprise could move when it utilized innovative designs and tools, prioritized research questions and resources, and engaged the right networks to answer those questions. Unfortunately, we also saw that 94 percent of studies were unlikely to yield meaningful evidence because they were too small or poorly designed.

With the end of the PHE, much of the trial infrastructure that coalesced around COVID-19 is disappearing or returning to its previous areas of focus. In many cases, pandemic-related flexibilities that enabled some of the innovation are in limbo.

There is, however, increased attention in both the public and private sectors to the importance of clinical trials infrastructure and knitting together more inclusive trial networks. Governments and nongovernmental organizations (NGOs) are promoting the adoption of more efficient and effective trial designs globally through guidance, policy, and standards. New organizations and initiatives are cropping up to develop resources and best practices, and to address barriers to some of the innovative designs and tools.

Clinical trials are an absolutely critical and extremely resource-intensive element of the process of biomedical innovation. Although there is no single right kind of trial to answer every question, and there will likely never be a single trials network or "czar," we cannot expect clinical trials to perform better during a PHE if we do not devote resources to improving their quality and the infrastructure that underpins them in "peacetime."

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.	Most COVID platforms and networks are returning to their previous areas of focus, although REMAP-CAP in the UK is turning to flu.	
	The White House is investigating how to ensure trial infrastructure is in place for PHEs and how it should be governed and coordinated.	
	CEPI has developed a $3.5 billion blueprint to develop a vaccine for the next pandemic virus based on lessons learned from COVID.	
Make more efficient and effective trial models the norm rather than the exception through public and private funding, incentives and policies, and regulatory guidance.	The National Institutes of Health (NIH) is considering halting funding for studies deemed too underpowered to produce meaningful results.	
	FDA's Complex Innovative Trial Design Meeting Program, renewed in FDORA, offers sponsors increased meeting opportunities.	
	The Good Clinical Trials Collaborative has developed, and Protas is implementing, guidelines promoting smart, randomized trial design.	
	CTTI released a suite of practical resources for designing and running master protocols.	
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.	FDA leadership outlined the benefits of streamlined point-of-care trial designs such as the RECOVERY trial.	
	ACT@POC was established to help drive implementation of large-scale clinical trials at the community level.	
	The UK government reviewed the commercial clinical trial landscape and will fund two to three Clinical Trials Acceleration Networks.	
	The private sector is investing in clinical trials and site networks, and new players are entering the space to improve efficiency and community engagement.	
Invest in making decentralized trials and the use of remote tools easier to adopt.	FDA has drafted guidance on decentralized trials, and CDRH is seeking public input on at-home use of medical technologies, which are trends accelerated by the pandemic.	
	Groups such as DTRA and Digital Medicine Society (DiMe) are enabling education, development, and sharing of best practices, removal of common barriers, and more.	
	Use of decentralized trial elements dropped from the pandemic peak but is rising again, industry is investing heavily, and studies of their value are being conducted.	
	Pandemic flexibilities that enabled decentralized clinical trials and telehealth are still in force for now, but their future is unclear.	
OVERALL GRADE: B-		

"One of the greatest benefits of the pandemic was really building data, digital, and tools into trials that we were reluctant to build in prior to the pandemic."
—Interviewee

B-

COLLECTION AND USE OF REAL-WORLD DATA AND EVIDENCE

Improvements in the use of RWD/RWE for product development and evaluation continue their pre-pandemic momentum, although attention is needed to the infrastructure required for such research.

> **"We've seen huge advances in using real-world evidence to make decisions for clinical trials. It can be invaluable to us in terms of making decisions as to what compounds, what programs, what indications to move into later-stage development. So, from our perspective, the benefits have been huge."—Interviewee**

The use of RWD/RWE in medical product development and evaluation was a discipline and a trend that was bolstered in the US by the 21st Century Cures Act in 2016, which required FDA to develop a framework and guidances for RWE that were in process when COVID-19 hit. The pandemic then starkly demonstrated the challenges to drawing sound conclusions from evidence not generated in a rigorous, randomized way, as well as the necessity of being able to learn as much and as quickly as we can about disease and treatments under real-world conditions and time frames. We learned a tremendous amount about the utility of RWD/RWE and brought together some remarkable initiatives to collaborate on standards and methods and improve the quality of both the data from real-world sources and the analytics.

Investment in real-world data and evidence has surged since 2020 (though primarily for Phase IV studies). Companies are increasingly using this information as much for internal decision-making as for regulatory purposes. Some of the platforms and approaches to improving the use of these tools that coalesced during the pandemic have persisted, and new ones have come into existence in the US and internationally. Congress continues to prod FDA through FDORA to provide additional guidance and resources to product developers, and FDA continues to finalize guidances and create new initiatives to facilitate effective understanding and use of RWD and RWE. Building and supporting infrastructure to more rapidly and efficiently conduct pragmatic trials, particularly those that can provide regulatory-grade evidence, remains a challenge.

This movement, which predates the pandemic, continues to unfold, with some gentle acceleration provided by the emergency response and relationships created in that crucible.

Sustain and deploy valuable RWD/RWE platforms and initiatives against other urgent public health questions.	N3C has not yet been directed at other health needs, although the National Center for Advancing Translational Sciences indicates it has plans to do so, specifically in rare disease.	
	Datavant's COVID-19 Research Database model is being extended to other public health priorities, such as chronic kidney disease.	
	The cross-industry Coalition for the Advancement of RWE through Randomized Controlled Trial Emulation (CARE) aims to demonstrate the value of RWE for regulatory decision-making.	
Invest in pragmatic trials networks to generate RWD/RWE rapidly.	The Patient-Centered Outcomes Research Institute continues to provide significant funding for pragmatic trials, including through the PCORnet research network.	
	The new European Health Data Space and DARWIN EU are intended to advance the use of RWD in research and regulatory decision-making.	
Integrate lessons learned into FDA's existing plans, frameworks, and guidance on RWE and technology modernization.	FDORA required additional guidance on FDA's use of RWD/RWE in a variety of scenarios.	
	FDA created a new Advancing RWE Program to provide greater meeting frequency for novel applications of RWE.	
	FDA's Technology & Data Modernization Plans have been updated, and a new Office of Digital Transformation has been created.	
OVERALL GRADE: B-		

"Divergence of findings teaches us as much about the data and populations as convergence of findings, and so we should try and understand divergence as well."
—Interviewee

C+

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.

> **"This used to be a topic that received a fair amount of lip service but limited action. I feel like there is a seriousness to actually make some systemic changes to produce measurable results."—Interviewee**

As we noted in early 2021, COVID-19 focused the public's attention on racial and ethnic disparities in health outcomes, access to health care, and trust and participation in research to an extent probably never seen before. These problems have been decades, if not centuries, in the making, and they have no quick or easy solutions. It is still too soon for any meaningful progress in addressing these long-term challenges based on our learnings from this pandemic; in fact, representation in trials continues to decline, and racial disparities in life expectancy continue to widen. We still have a very long way to go. But attention has been sustained in the near term, actions are being taken by players across the ecosystem, and some signs of limited progress are evident.

NIH is building on its experience engaging diverse research participants with a new strategic plan and an initiative to address diversity and inclusion in the research workforce. In response to a congressional mandate, FDA is implementing requirements for diversity action plans from sponsors, which helps drive industry's focus. The Centers for Medicare & Medicaid Services (CMS) is requiring representative recruitment to trials for coverage of new products. Companies are committing significant resources individually and in partnership to improve diversity in a variety of ways. Organizations of various stripes are developing tools and resources to help stakeholders understand the need for, plan, and execute efforts to diversify trials. (If it is possible, perhaps too *many* sets of recommendations and toolkits are being created, which has inspired FasterCures to mobilize with the National Academies, the Multi-Regional Clinical Trials [MRCT] center, and CTTI in a "Diversity Convergence Project" to align goals and prioritize areas for national collective action.)

Many challenges and issues remain to be overcome if we are to mitigate the impacts of decades of exclusion and mistrust. Focus and resources must be sustained for the long haul so that positive change in the indicators of success can be achieved. Capacity must be built in communities so that they can be fully engaged and represented in the research enterprise in a sustainable way. However, in the near term, there is some hope that commitment and resources will persist.

Build relationships and trust with individuals and partner organizations in minority communities.	Black/African American and Hispanic patient representation in trials has continued its decline since 2012.	
	A National Academies study demonstrated the health and economic cost of lack of diversity and the willingness of under-represented populations to participate in research if asked.	
	NIH is building on its work in the *All of Us* Program with its UNITE program and a strategic plan for diversity, equity, inclusion, and accessibility.	
	The NIH Clinical Trials Diversity Act has been introduced in Congress but not moved.	
Bring leadership, resources, and cohesive plans to set priorities and create accountability across stakeholders.	FDORA required and FDA issued guidance on diversity action plans focused on up-front planning and goal setting.	
	The White House issued an Executive Order requiring agencies to make advancing equity a central component of their decision-making frameworks.	
	Industry is initiating and funding individual and collective efforts to set goals and demonstrate best practices.	
	Organizations such as FasterCures, MRCT, and CTTI have provided recommendations and extensive resources.	
Improve data collection and use.	The White House's Equitable Data Working Group outlined a strategy for increasing the data available for measuring equity and representing diversity.	
	The DEPICT Act requires enhanced data reporting on trial participant demographics.	
	Tools such as the Health Equity Tracker and Health Equity Data Sandbox are enabling insights, policy change, and solutions development.	
	A new Fair Inclusion Score aims to create transparency around participant demographics and quality measures for inclusion and diversity.	
Broaden eligibility criteria and change study designs to include more participants.	FDA guidance emphasizes acceptable eligibility criteria and trial designs that can improve diversity in trial populations.	
	The cancer community is advocating for reforming recruitment criteria and using RWD to define eligibility.	
	GSK studied historical data to demonstrate best approaches for designing trials to achieve diverse enrollment.	
Bring trials to communities through site selection, creation of trial networks, and use of remote tools.	Industry is making commitments, implementing pilots, and developing tools to expand research networks and sites.	
	DiMe has developed a framework and resources to ensure inclusivity in trials' use of technology.	
OVERALL GRADE: C+		

"We've seen much greater connection to our obligations to ensure that our medicines are being tested in diverse populations."—Interviewee

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