Federation of American Scientists

Strategies to Systematically Strengthen Clinical Trials Infrastructure

Thank you for the opportunity to provide information to the Office of Science and Technology Policy (OSTP) on key questions regarding state development of research infrastructure and processes for emergency clinical trials (ECTs). Overall success on this front requires success in a series of important stages: increasing federal capacity for collaboration within and across government; innovating to address technological limitations of existing infrastructure; improving participation through community-engaged research; issuing updated regulatory guidance for products developed through emergency trials; and investing in evidence synthesis, implementation, and communication. We refer to this as the I5 approach.

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Increasing Federal Capacity for Efficient Collaboration

This section will address questions relevant to building a centralized U.S.-level governance structure, focusing on designs that will be suitable for both pre-emergency coalition building and infrastructure development as well as emergency management (questions 1a, 1d, 1f).

The myriad extant partnerships across government agencies and external institutions provide a series of possible roadmaps for governance of an emergency clinical trials effort. The most common interagency efforts can broadly be structured as falling on a collaboration to coordination spectrum. Collaborative efforts—like the Interagency Council on Evaluation Policy—are those in which members participate in a given arrangement on relatively equal footing. Coordination efforts—perhaps the most significant example being the establishment of the Director of National Intelligence—are those in which one or two agencies or individuals are given authority and funding to shape and delegate cross-institution efforts. To build a governance structure that is positioned for success in both an emergency situation and public health "peacetime" requires components of each. Operation Warp Speed (OWS) offers valuable lessons for designing inter- and extra-agency partnerships that can meet both challenges.

OWS's efficiency and success during the early stages of the COVID-19 pandemic draws a direct parallel to the activities that would be required of a longer-standing emergency clinical trials structure during an acute emergency. OWS was established primarily as a joint partnership between the Department of Defense (DOD) and HHS, and leveraged several existing relevant

HHS offices and capabilities to provide guidance, data, and resources at various stages: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA). This general structure ensured that OWS was a science-driven program backed by the organizational capacity and resources of the DOD. Further, it linked auxiliary offices to the effort without confounding the chain of command, securing buy-in from across the government.

OWS-like structures are maximally effective in situations where a pressing need and specific, time-bound goal can orient partner institutions towards a shared mission. Yet in order to address the many challenges that OSTP identified in this RFI, such a structure should be stood up well in advance of any emergency, and active programs of relationship formation, solutions R&D, community and research site engagement, regulatory innovation, and communication preparedness will need to be built. In "peacetime," with fewer external motivators, there is a risk of institutional ossification—such that member organizations may not pursue recommended goals and reforms and there will be limited muscle memory when an emergency arises. Even if the group's leadership is motivated and active in the interim period, there is an additional risk that member institutions will prioritize the pursuit of contradictory programs or priorities at the expense of the partnership's cohesion and success. Thus it is critical that leaders of the broader governance structure—whatever form it takes—are imbued with sufficient authority and funding to pursue ambitious programs, and are accountable for meeting goals and timelines.

Such programs, though initiated by a centralized process, should source advice and collaboration from a wide variety of relevant partners; medical systems, federal health centers, research funding agencies, patient advocacy groups, biotechnology start-ups, established pharmaceutical companies, etc. all hold vital insight into these initiatives. To ensure that these partners have clear lines of communication and engagement, it will be beneficial for the government effort to have a transparent leadership and responsibility structure, rather than a decentralized collection of participants.

Innovating to Address Technological Limitations of Existing Infrastructure

This section will address questions relevant to the collection and analysis of data for emergency clinical trials, focusing on the role agencies can play in supporting new technological and methodological frameworks (questions 2i, 1k, 5).

Regardless of the level of buy-in that can be obtained across agencies and private partners, there exist limitations to the United States' current medical research infrastructure that will impede the efficient and effective management of data in an emergency context. To facilitate large-scale, decentralized emergency clinical trials, there must be a push across health and science agencies to support research and development across the data collection, management, and analysis pipeline.

When aiming to advance rapid, light-touch data collection in emergency trial contexts, decentralized or registry-based approaches can offer convenience for patients and

investigators, increased ease of scaling, and improved access to a diverse pool of patients. The feasibility of decentralized data collection at scale has been advanced with recent technological developments (e.g., health apps, electronic patient-reported-outcome tools, code standardization, and wearable devices). But the substantial variability in data quality and interoperability across tools and companies could hamper their widespread adoption. Collaboration across agencies could make decentralization much more feasible at scale. ARPA-H should consider programs to drive down cost and drive up accuracy of wearable devices and medical apps, especially for diverse populations; the ONC should undertake explicit expansion of its guidelines on interoperability into these new technological contexts to facilitate seamless integration for emergency research; and to ensure meaningful change rather than minimal compliance, NIST should institute research programs to study real-world effectiveness of data integration and develop standards for adoption. These recommendations apply equally (or more so) to traditional centralized data collection; indeed, interoperability of electronic health records (EHR) will be especially important in emergency contexts, and should be strongly incentivized through both requirements and real-world evaluations.

Centralized data management resides on the other side of the coin from decentralized data collection. The importance of centralized data systems was highlighted during COVID-19, when the accessibility of the NHS's pared down, country-level medical records data enabled the UK's Recovery Trial. This trial was vital for determining which existing medications were most effective for treating COVID patients and likely saved hundreds of thousands of lives. While the U.S. is unlikely to pass legislation for its own NHS in the coming years, collaboration between government agencies, private medical systems, and health records companies could lead to great strides in the U.S.'s capacity to transfer and store large quantities of simple health information to facilitate research in emergencies. With companies like Verily and Epic already building out their own large-scale trial infrastructures, the NIH and ARPA-H are well-positioned to prioritize ambitious goals for a national (emergency) clinical trial infrastructure. The federal government can also utilize its programs that fund rural and low-capacity hospitals and clinics to build out technical infrastructure needed to reach the most vulnerable populations typically missed by clinical trials held in large urban centers.

Finally, the development and approval of state-of-the-art methods for large-scale data analysis are critical for ensuring that emergency trials can be completed—and learnings can be implemented—as efficiently as possible. The UK's Recovery Trial again provides a strong example of a highly efficient multi-intervention protocol. But in the absence of a centralized health system like the NHS, the U.S. will need to invest heavily in new data analytic approaches to build internal capacity. Here, again, multiple agencies should be coordinated to pursue this effort. The FDA currently engages with innovative trial designs through its Complex Innovative Trial Design Meeting Program (CID Pilot Meeting Program), which makes it easier for companies to pursue novel designs by presenting case studies to the FDA for review and discussion. Since methods tailored to large-scale, collaborative emergency trials are unlikely to be incorporated into company-specific drug trials, the scope of this program should be expanded to allow academic and corporate methodologists to present hypothetical designs that can be pre-approved in principle rather than as part of a specific case study. The European

Medicines Agency conducts similar investigations and provides qualification opinions for analysis procedures. Beyond trial designs, there is a great need for advanced statistical approaches for EHR data analysis; ARPA-H should consider supporting a program focused on efficient pipelines for cleaning, de-identifying, integrating, and analyzing complex EHR datasets while preserving patient privacy and institutional information. EPIC has shown the power of real-world evidence analysis at a massive scale through their COSMOS platform, studying retrospectively critical care questions like effectiveness of COVID-19 treatments. Rapid investigations of clinical care practice in times of emergency and "peacetime" will enable systematic and ongoing audits of the way healthcare is delivered, to ensure the best quality and most equitable care.

Improving Participation Through Community-Engaged Research

This section will address questions relevant to ensuring equity in clinical trials infrastructure, focusing on the potential for "warm-base" sites to ensure distributional equity of clinical research. (questions 2b, 2c, 3a).

To build up "warm-base" research across the country, OSTP should look to blossoming models of regional engagement sparked by the recent growth of infrastructure funding through the American Rescue Plan, Infrastructure Investment and Jobs Act, and CHIPS and Science Act. These place-based economic development policies focus on investing in communities to create thriving entrepreneurial ecosystems and industries. While funded by the federal government, these programs allow for communities to build infrastructure that works for them, versus having to implement a one-size-fits-all model that is likely to not serve communities' needs. Successful clusters will often: proactively develop multi-year strategies, include a diverse array of stakeholders, rely on evidence to form strategies, see federal grants as ways to build capacity, and research peer communities to identify best practices. We can translate these learnings from cluster development to building out warm-base research, noting that federal investment can spur meaningful private-public partnerships between universities, corporations, start-ups, capital providers, and local governments that help clinical research drive benefits for community members and economies. For example, findings from clinical research can be translated into tangible products through private start-ups and companies. Ongoing research into the health problems that impact a community's well being and ability to thrive economically will drive technology, programmatic, and policy solutions that improve individual quality of life, especially for those most marginalized.

To maximize benefits to communities in underserved areas and meet new statutory requirements for diversity in clinical trials, clinical trial sites should involve community members in the planning stages of trial design and implementation. Our understanding of which problems need "solving" are shaped often by those with the most power and influence, rather than those facing the greatest health inequities. This could look like 1) securing letters of intent with community based organizations (CBOs), with regular compensation guaranteed, to engage collaboratively in execution of trial recruitment, with clauses for emergency recruitment, 2) setting up community advisory boards with communities in decision-making roles to steer the broad directions of trial recruitment, and 3) prioritizing hiring community members to develop

their resources and capacity for clinical trial deployment. If warm-base research is established through a federal grant-making process, grantees should be required to report back on these strategies to ensure proper community engagement is being conducted and show how that has shaped the timeline of the project. Finally, community advisory, such as through an advisory board, should also be a part of the larger execution of clinical research infrastructure; patient representatives could become members of the federal governance board.

Further, it must be noted that to increase engagement in clinical research, trial sites will need to be able to provide meaningful compensation for participation. Trial diversity is often hard to achieve because the most underrepresented communities are both economically unable to take the time to participate due to work, childcare barriers, travel barriers as well as hesitant to engage because of historical exploitation of vulnerable communities by the medical research enterprise. Recent research has found that to engage the most underserved communities, compensation on the order of $500 was necessary to increase likelihood to participate in clinical research. While this order of financial compensation may be difficult to institutionalize, especially in an emergency situation where thousands of people will participate, it does speak to the need to offer tangible resources to meet people's needs. Finally, leaders in expanding clinical trial diversity at the Recruitment Innovation Center at Vanderbilt University have found that it is vital to carefully consider the inclusion/exclusion criteria that might bar people from participating, such as if insurance is required or documentation of citizenship needed. Paying for medical care may increase the overall cost of the endeavor, but will make it more broadly accessible to underserved populations that are often also underinsured or uninsured.

Finally, while digital health technologies will be critical to the expansion of trial infrastructure, they should be used with the utmost consideration for data privacy, broadband access, and recognition of potential inequities baked into the data collection tools. Telehealth technologies have been found to share sensitive health information with data brokers, as the Health Insurance Portability and Accountability Act (HIPAA) has not been kept up to date for telehealth. Cybersecurity is vital to ensure trust in the research process, especially for communities that have been historically harmed by medical research. This could look like developing a "Patient Data and Tissue Bill of Rights" to ensure that trials are structured around data protection and issuing regular compliance notices to trial operators to reiterate providers' legal obligations with respect to patient health-data rights. Further, not all communities can access digital technologies due to a lack of access to the internet. Broadband expansion should be considered as a necessity to have decentralized trials infrastructure. Finally, digital health technologies, from apps to wearable devices, have been shown to have embedded biases that can impact the accuracy of collected data. From computer vision technology being less accurate on dark skin, such as for skin cancer recognition, to pulse oximeters overestimating oxygen saturation, these biases can skew data sets for already vulnerable populations, leading inevitably to less effective treatments. Digital health equity principles should be created for tool procurement to ensure all products purchased for clinical trial use are guaranteed to work on the diversity of the American population.

The following case studies highlight a series of strategies to increase diversity amongst study participants and to expand clinical research sites into underserved areas, for both emergency trials and warm-base research efforts:

Partner directly with communities to coordinate research investigations:

1. Healthy Flint Research Coordinating Center (HFRCC): A partnership between community organizations and academic institutions focused on equitable relationships between communities and academia. HFRCC evaluates and must approve all research conducted in Flint, Michigan. HFRCC helps design proposed studies that would align better with community concerns and context and ensures that benefits flow directly back to the community. Health equity is assessed holistically: considering the economic, environmental, behavioral, and physical health of residents. Finally, all work done in Flint is made open access through this organization. From these efforts we learn that communities can play a vital role in defining problems to solve and ensuring the research will be done with equity-in-mind. This will be especially important at "warm-base" research sites that are investigating solutions to chronic diseases, which are most urgently impacting underserved communities.
2. Patient-Led Research Collaborative: Patient-led research initiative for studying the impacts of long COVID on patients and searching out treatments. Using large, patient support groups, they have conducted online surveys to systematically study LC populations and understand the impacts of disease on life, work, and return to health. They have found that most patients continued to experience significant disability that impacted their ability to return to normal life. Their work highlights the need to take LC seriously as a disease, identify meaningful treatments, and design policies that ensure LC patients can financially support themselves as they recover. The patient voice should play a key role in the innovation process, especially understanding the lived experience of managing chronic conditions. While treatments are highly desired, patients also need policies that support their recovery (such as work from home) as well as safety nets (like disability benefits) that ensure they do not fall into poverty due to their conditions. This speaks to the need for "warm-base" research to not just be about testing medical products, but also programmatic, infrastructural, and policy interventions that tackle the social determinants of health
3. Community Partners in Care: Community Partners in Care (CPIC) was a collaborative research project funded by the NIH, which sought to improve depression care in primary care settings through community-engagement. It compared two ways of supporting diverse health and social programs in under-resourced communities to improve their services to depressed clients: 1) technical assistance coupled with culturally competent community outreach and 2) 4-6 month planning process between agencies and community members to fit the depression programs to community needs. They found that community-engaged processes like the 4-6 month planning period were more effective in decreasing homelessness, improving quality of life, increasing physical activity, and decreasing out-patient visits and hospitalizations. Partnering directly with community organizations can help to evaluate new technologies in the real-world setting

and ensure that the technology comes with a culturally-responsive implementation plan. These community organizations should be compensated for their expertise, given their potential to increase diversity in trials.

Leverage community and patient-review on study protocols to increase buy-in:

4. California Institute for Regenerative Medicine's Patient Advisory Infrastructure: Patients hold 12 of 29 slots on the governing council, including the chair and vice chair. This council approves funding of all grants. All 68 clinical advisory panels also require patient advocates. They have found that while there was initial skepticism about what patients could bring to research processes, they have become vital members of the reviewing effort. Patients have ensured that 1) more risky initiatives get funded 2) impact on patients is discussed in research efforts and 3) skepticism of strategies that only consider human physiology but neglect behavior. Patients' experiences living with disease is often left out of the conversation about high-impact health innovation and clinical trials design. Advocacy boards which give patients the power to decide research directions can ensure that voice is mobilized to fund research that will best enhance patient's lives as well as ensure engagement is always ready to ramp up in the event of an emergency.
5. BMJ Patient and Public Partnership Initiative: *The BMJ* has patients and patient advocates influence day-to-day decision making by championing partnerships with patients in healthcare. Their journal includes patient and public review alongside the conventional peer-review process. Patients in their evaluations identify the wider impacts of illness, burdens of treatment, how conditions are self-managed, and whether treatments are practical. They are also critical of statements without strong evidence, as well as statements that disparage patients. Now, *The BMJ* also requires authors to specify how patients were involved in the research process, from question setting to design to implementation to dissemination. Now those involved in this effort are working to expand patient-voices across health-publishing. Patients have a tremendous amount of knowledge about the broader impacts of illness and can ensure that treatments being tested are practical given the burden of managing the disease. Having these fundamental practices as a part of clinical trials / "warm-base" research guidelines will ensure community outreach becomes a part of the research process.

Utilize technologies familiar to patients to expand access to trial participation:

6. Count Me In: A patient-partnered cancer research initiative that empowers patients to share cancer samples, clinical information, and experiences to accelerate the pace at which new discoveries are made. They use online surveys and sample collection kits mailed directly to patients to understand rare cancers. They are working to study large groups of patients across cancer types, treating institutions, ages, and other demographics to represent the full diversity of cancer patients and their experiences, so that developed solutions have a greater impact on everyone. Their work on rare cancers (25% of adult tumors) was published in *Nature Medicine*, where they were able to see

patterns amongst geographically dispersed patient populations. By working to reduce the barriers to participation in research, CMI believes it will be much easier to study rare diseases and enable new discoveries. Understandings of rare diseases are especially limited by data, which can be hard to collect when populations are small and regionally dispersed - thus any "warm-base" research in this area must be decentralized. Through reducing barriers to participation, patients can play an active role in submitting data that can accelerate healthcare discoveries, regardless of where they are located. Further, because regular communication with participants is a major focus, patients feel connected to the larger research agenda, increasing willingness to continue participating.

Issuing Updated Regulatory Guidance for Products Developed Through ECTs

This section will address questions relevant to regulatory guidance on products investigated through emergency clinical trials. (questions 1i, 2e, 6c).

There should be regular and ongoing communication with regulatory bodies from the centralized governing bodies, given the demands for accelerated approvals and emergency use authorizations for products developed through ECTs. There are a series of trade-offs to consider when approving new medical products in times of emergency. For example, the delay in formal vaccine approval until long after widespread adoption increased vaccine hesitancy due to concerns about taking experimental medicines. Further, this speaks to a lack of public awareness about the relationship between the FDA and sponsors when a product is under emergency use authorization (EUA). EUA products still require phase 1-3 trials as well as a post-market evaluation period to ensure products meet standards for safety and efficacy.

The FDA could consider "rolling-reviews" of clinical data as well as real-world data, as was employed in the United Kingdom and European Union, that allow for regulatory agility in times of crisis. In rolling reviews, data is submitted and reviewed as they become available before the full data package is available. This approach will require a closer collaboration and more intense interaction between the sponsor and the FDA, but is beneficial for accelerating regulatory approval as changes can be made to study protocol along the way versus requiring new, costly studies after regulatory consideration. Living evidence, a strategy described further in the next section, could be an effective tool for collecting this data for examination and analysis by regulators to make critical decisions on the efficacy and safety of products and then communicate those decisions out to the broader public. There is still a risk that products authorized under EUAs could be later found to be less effective, but with a more concrete process for regular review of the data the FDA can pull these products rapidly from the market to prevent any risks to population health.

In times of emergency, data submitted to the FDA could be made available for examination by the broader scientific community. Currently, data submitted to the FDA as part of its regulatory-approval process is kept as a trade secret and not released pre-authorization to researchers. Releasing the data via an FDA-invited "peer review" step in the regulation of high-risk technologies, like automated decision-making algorithms, Class III medical devices,

and drugs, will ensure that additional, external rigor is applied to the technologies that could cause the most harm due to potential biases or data gaps.

Finally, given the national impacts of a medical emergency like the COVID-19 pandemic, it is vital for our tools to work when scaled up to the entire U.S. population. This will not only ensure sites engage in Good Clinical Practice for safety of participants, but also carefully consider equity as a key priority in clinical trial designs. This is especially important with the new statutory requirement for diversity action plans for drug clinical trials. While ensuring equity and generalizability of a tool could slow down progress towards an authorized product, it can reduce hesitancy to uptake and adoption once the technology is at scale as well as mitigate adverse events that further drive polarization on medical products like vaccines. For example, the broad exclusion of pregnant people from vaccine clinical trials led to increased hesitancy to get vaccinated because of the lack of evidence, despite retrospective trials later finding that vaccination was safe during pregnancy. 30% of pregnant people have yet to complete their primary series of the vaccine and only 15% of pregnant people have been boosted as of December 2022, according to the CDC. Further, there should be substantial diversity action plans required of clinical trial operators in order to sufficiently power the study to allow for subgroup analysis as well as multi-factor analysis by race and ethnicity, gender, and age. Finally, for algorithms, multi-site analysis is critical, given the differences amongst clinical populations as well as clinical infrastructure. For example, an algorithm developed at a wealthy hospital using the latest medical imaging technology may have images of much different quality than +15 year old equipment at a federally qualified health center. Thus, algorithms could fail to work at scale in the multitude of contexts necessary for national roll-out. Training should focus on best practices for recruiting diverse pools of participants, leveraging the existing capacity of organizations focusing on diversity, equity, and inclusion in clinical trials such as the Multi-Regional Clinical Trials Center and Recruitment Innovation Center. Modalities should include not only webinars, but also site-specific training, where experts (including leaders in CBOs recruiting people for trials) are paid to travel to sites to provide concrete advice and strategies on sponsor's diversity plans.

Investing in Evidence Synthesis, Implementation, and Communications

This section will address questions relevant to outlining best practices for clinical trial design, and speak to the need for "warm-base" research to also test best practices for scaling up interventions, such as communication and distribution strategies. (questions 1g, 3b).

We live in a time of veritable "scientific overload". The number of scientific papers in the world has surged exponentially over the past several decades and millions of newspapers are published every year. This flood of papers has never been as acute as it was during the COVID-19 pandemic, with thousands of papers published every day, of massively varying quality. Making sense of this deluge of research presents a formidable challenge in a non-emergency context. In an emergency, when the knowledge is growing every day and evidence-based decisions need to be made quickly, the typical process of *(i) scouring the literature for relevant findings, (ii) separating out low-quality or fraudulent research, and (iii) synthesizing studies' results into a format that can inform decision-making* is untenable. With

researchers, policymakers, medical practitioners, patients, and stakeholders all desperate for authoritative information, the lack of up-to-date synthesis can be disastrous.

Living Evidence provides a framework for addressing these weaknesses by treating knowledge synthesis as an ongoing rather than static endeavor. By combining (i) established, methodical methods of summarizing science with (ii) continuous workflows and tech-based solutions for information discovery and processing, living evidence approaches yield a high fidelity signal of science. Such approaches are relatively new, but have already proven demonstrably valuable. For instance, living evidence "helped chart a route out" of the worst stages of the COVID-19 pandemic by providing rigorous and up-to-date knowledge synthesis. Resulting products—like this living systematic review and meta-analysis on drug treatments—were enormously valuable for communicating complex and fast-moving science. In recent years, the World Health Organization has launched a large-scale effort to embed living evidence across its whole portfolio, Wellcome is investing in building Living Evidence resources for mental health research, and AHRQ is incorporating living systematic reviews into their workflow. Such efforts illustrate the rapid adoption of this model by major health sector actors; yet widespread support and capacity-building for living evidence in biomedicine and public health remain rare.

As part of the effort to develop infrastructure for emergency clinical trials, OSTP should explore opportunities to embed living evidence—both its ideals and its practitioners—into relevant agencies, and to fund external efforts housed within public health partner institutions. Importantly, the value of living evidence to emergency trials is not limited to communication of trial results and treatment recommendations after the fact. Living databases for knowledge synthesis would be a valuable asset for tracking characteristics of potential trial sites and assessing readiness, monitoring the evidence base for promising devices for decentralized data collection, promoting and advancing best practices for designing efficient clinical trials, and even monitoring emerging biological threats. In all cases, an authoritative source for up-to-date knowledge would provide an invaluable service to both the government and U.S. citizens.

On the topic of improving "warm-base" research, there is a need to think about ways to implement evaluation of new health interventions in a realistic setting (i.e., the clinic, the hospital, at the point of care) on large, representative populations is a necessity for equitable, safe medical technologies. It should be considered as a part of developing an ECTs protocol. It is challenging to know once new technologies are deployed into the clinic how they are being used and if they remain as effective at scale as they do in a randomized controlled trial. Even if a new intervention works for diverse populations, access issues may stand in the way of its broad uptake by populations, as seen during the COVID-19 pandemic with diagnostics and vaccines. Finally, there are many public health problems that cannot be addressed by a single intervention, such as widespread health misinformation and lack of culturally-competent care strategies. Multi-intervention trials are still a nascent area of research, especially as they rely on novel communications strategies alongside new tools and interventions. FAS recommends funding large scale trials of communication, distribution, and implementation strategies for novel health interventions.

Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) can be seen as a model for creating testbeds for community engagement on communication, distribution, and implementation. RADx-UP was created to address the issue of vulnerable and historically underserved communities not able to access COVID-19 diagnostics. By deploying rapid grants to initiate community-engaged research and directly funding CBOs to increase capacity for COVID-19 testing initiatives, RADxUP advanced communities' abilities to respond to health crises in ways that worked for their populations. RADx-UP found that for people to access these novel technologies: equitable access had to be ensured, culturally responsive communication and messaging needed to be made to patients, and payment reforms needed to be made to support innovative care management. Without these systemic efforts, a new technology will fail to reach everyone, especially in times of need. Another important finding of this initiative was the importance of data strategies to locate disparities, and then search out context-specific ways of mitigating the barriers, such as the use of mobile units in healthcare deserts. RADx-UP shows that equity efforts cannot be reactive, federal agencies must think proactively about how equity is embedded in the planned roll-out of a technology or intervention for public health.

Thank you for providing this opportunity to respond on ways to strengthen American clinical trials infrastructure. If there are any questions about the content of this memo, please direct them to Grace Wickerson (gwickerson@fas.org) and Jordan Dworkin (jdworkin@fas.org).

Sincerely,

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