ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

February 4, 2022

The Honorable Patty Murray
Chair
HELP Committee
428 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
HELP Committee
428 Russell Senate Office Building
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr,

Thank you for the opportunity to provide feedback to the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) discussion draft.

The Association of Clinical Research Organizations (ACRO) is made up of the world's leading clinical research and technology organizations. Our member companies are involved in the majority of clinical trials in the United States and around the world. ACRO members provide an array of specialized services across the entire spectrum of drug, biologic, and medical device development—from discovery, pre-clinical, proof of concept, and first-in-man studies, through post-approval and pharmacovigilance research.

We appreciate the hard work that went into developing the PREVENT Pandemics Act discussion draft and would like to offer both general comments and specific suggestions that would further bolster this important piece of legislation.

General Comments

ACRO is supportive of the need to evaluate and implement lessons learned from the COVID-19 pandemic to be better prepared for future pandemics. In many fields, the COVID-19 crisis has accelerated innovation out of necessity. In the clinical trial space, temporary regulatory flexibilities have accelerated the deployment of innovative solutions including elements of decentralized clinical trials (DCTs), that would improve access to trials and ease participation burdens for patients if made permanent. Making these flexibilities permanent would enable future trials to be more resilient to emergencies and pandemics, allowing for a smoother transition to a mostly remote model, ensuring continued monitoring of enrolled patient safety and maintenance of data integrity. Additionally, these policies make clinical research more patient-centered by reducing burden on patients and clinical trial sites, while expanding patient access to trials beyond traditional urban centers.

The COVID-19 pandemic also made us in the industry think harder about how we can ensure clinical trials are representative of the world we live in. COVID-19 vaccine trials were, overall, highly successful at recruiting diverse populations and producing meaningful data in record time, without sacrificing safety or efficacy standards. ACRO and its members are committed to improving diversity and inclusion in clinical research and one way to do

this is to improve the availability of and access to patient health data sources. Decentralized clinical trials would help in this regard as well, as many DCT components improve a trial's ability to be immersed within the communities they are aiming to serve.

Specific Comments

TITLE II—IMPROVING PUBLIC HEALTH PREPAREDNESS AND RESPONSE CAPACITY	
Subtitle B – Improving Public Health Data	
Sec. 211. Modernizing bio-surveillance capabilities and infectious disease data collection **Sec. 213.** Supporting public health data availability and access	• We suggest that integration of relevant data systems, including public health surveillance data, is crucial to improving the public health response. Similarly, allowing researchers access to public health databases and information would help optimize planning and execution of clinical trials. Data collection and reporting obligations should focus on entities that typically have face-to-face encounters with individuals.
TITLE V—ENHANCING DEVELOPMENT AND COMBATING SHORTAGES OF MEDICAL PRODUCTS	
Subtitle A – Development and Review	
Sec. 501. Advancing Qualified Infectious Disease Product innovation	• The section on the Qualified Infectious Disease Product (QIDP) designation is solely focused on infectious disease products and biologics intended to treat serious or life-threatening infections. ACRO suggests enlarging this section to include products and biologics intended to *prevent* such infectious diseases (i.e., vaccines, pre- and post-exposure prophylaxis). • We also suggest adding "antivirals" in addition to antibacterial or antifungal products on page 158, line 17. • Page 159, lines 9-11 currently state "…requires clinical data…to demonstrate safety or effectiveness…" The use of "**or**" here should be replaced with "**and**".
Sec. 502. Modernizing clinical trials	**General Comments** • The publication of proposed FDA guidances (re: digital health, decentralized trials, alternative study designs) to improve the conduct of clinical trials is critical for sponsors, clinical research organizations (CROs), technology providers, research sites, and other stakeholders to expedite product development during pandemics/epidemics/outbreaks to facilitate expedited product development and data review. • Guidance regarding expanding the use of electronic methods in clinical trials beyond eConsent and other methods (e.g., e-diary cards, patient-reported outcomes data collection, telemedicine, lab samples collection, etc.) and elucidation of how these can be used to facilitate overall remote clinical trial oversight and reduce operational/logistics

	burden (e.g., monitoring, source data verification, electronic data exchange between sites and participants, etc.) would be valuable. • FDA guidance should include considerations and recommendations for "hybrid" clinical trials utilizing centralized and decentralized approaches in tandem. • Guidance and recommendations for the use of digital health technologies to facilitate the inclusion of diverse and underrepresented populations is a priority. • ACRO suggests that processes should be created to incentivize physicians to make patients aware of relevant clinical trials and to refer patients to appropriate clinical trials as a standard of care to increase patient awareness and engagement. Such a process could also include opportunities for primary care providers to become investigators in clinical trials. • All medical insurers should be encouraged to use EOBs and other communications tools to make patients aware of relevant clinical trials as a care option. • The FDA should encourage more focused and streamlined efforts to identify and routinely incorporate patient-centered endpoints into clinical development programs. • The FDA should encourage sponsors to develop a rating score from patients about their overall experience as a standard output of clinical trial participation. This rating could be made publicly available and easily accessible as part of the awareness campaign for patients. • Further clarification by the FDA of a framework for novel clinical trial designs (platform trials, cohort expansion, adaptive study designs, etc.) to optimize evaluation of products at a sponsor level and across sponsors would be helpful. • Innovative seamless designs guidance to clarify "operationally seamless" (logistics) approach vs. "inferentially seamless" designs (data pooled between phases) would be beneficial. **Clarifying the use of digital health technologies (DHTs)** • From a digital health technology perspective, the incorporation of eConsent and telehealth should be made available as options for all clinical trials, provided that trial subjects are given choice to opt in or out of these methodologies through the lifecycle of a study. • It will be important that guidance either define the meaning of "validated" digital health technologies (page 159, line 19) and the data needed to support validation or, this term should be changed to say "fit-for-purpose/fit-for-use." The use of "validated" may lead to confusion as DHTs are so varied in use cases. • Recommendations should be made by the FDA for the protection of trial participant data, including provisions for securing data against cybersecurity threats. • Note that digital health technology may limit participation for certain participants, particularly those who are geriatric and may have technical and vision/hearing challenges; hybrid trial approaches may be applicable here.

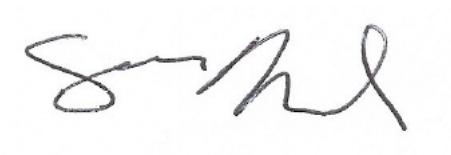
	• Early engagement between sponsors and FDA is important but may be limited, so it will be important that there be clarity and specificity around best practices for early engagement. • There may be unique considerations for the use of DHTs in pediatric trials—with the potential for separate components for the pediatric patient and their parent. Specific considerations for the pediatric population should be included in guidance. **Advancing decentralized clinical trials** • Home nursing should be incorporated as an option, and sponsors should be encouraged to develop protocols that permit some visits to be home-based. For example, physical examinations at home could be allowed so that a qualified and trained home health professional can conduct targeted/abbreviated physicals and could also utilize the telehealth capabilities available. • With respect to remote data collection, it will be important to ensure secure reporting of patient data and to ensure protection from cybersecurity threats. • There should be a focus on the definition of appropriate clinical endpoints in decentralized trials, if they are different from those in non-decentralized trials, and the validation needed for those endpoints. • Specific considerations for the pediatric population with respect to decentralized trials should be included in the guidance. **International harmonization** • International harmonization efforts related to the modernization of clinical trials will be particularly important with respect to the Pediatric Study Plans and Pediatric Investigation Plans. The guidance should address the logistics of these efforts. • With respect to decentralized trials, ACRO has been actively engaged with regulators in the United States, United Kingdom, and Europe to help ensure harmonization across various regulatory authorities—we remain supportive of further efforts to encourage this.
Sec. 504. Third party test evaluation during emergencies	• Guidance on expedited development/qualification/validation of laboratory assays and standardization of diagnostic methods to facilitate data comparability during a public health emergency would be valuable.
Sec. 505. Facilitating the use of real-world evidence	• The legislation in its current form does not effectively tie together the concepts of real-world evidence and decentralized trials. The section on decentralized trials focuses primarily on digital health solutions; however, one could also leverage RWE from emergency medical records or other patient health data sources to streamline the randomized control trial and increase the level of pragmatism. It is not clear whether those are included in the concept of “digital health.” It will be important, for example, to understand the role of external control arms and natural history data in support of authorizations for emergency use.

	• While there is mention of "recommendations for how to streamline trial logistics and facilitate the efficient collection and analysis of clinical trial data, including any planned interim analyses," the concept of pragmatic trials (and potentially large simple trials) is missing.
Sec. 506. Advanced platform technology	• The development of advanced platform technology will require collaboration from multiple stakeholders—including CROs, technology providers, sponsors, etc.—and those collaborations should be supported to move this technology forward.
Sec. 507. Increasing EUA decision transparency	• The publication of real-time data will facilitate the implementation of subsequent trials.

Conclusion

Thank you again for the opportunity to comment on this important legislative package. ACRO and its members stand ready to assist you in developing policy informed by the clinical research, data, and technology expertise that ACRO members possess. Please do not hesitate to contact us if you need more information or would like to discuss any of our above comments further; we would be happy to provide language suggestions in areas where not already provided.

Sincerely,



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