February 4, 2022

The Honorable Patty Murray
U.S. Senate
Committee on Health, Education, Labor & Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
U.S. Senate
Committee on Health, Education, Labor & Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

We commend the Committee for recognizing the importance of modernizing clinical trials in the discussion draft of the *PREVENT Pandemics Act*. Creating opportunities for more diversity and patient engagement is long overdue. We agree with the Committee that obviating the need for travel time, lost wages and childcare/eldercare through use of digital technologies will significantly increase the pool of potential participants. It is also critical with respect to advancing health equity by accounting for such logistical and other participant-related factors that could limit participation. Section 502 of the bill represents a major step forward by the federal government to improve recruitment, retention, and participation in clinical trials.

We are writing to encourage the Committee to consider an additional requirement of the FDA to include in this section of the legislation. State regulators have a role in breaking down additional barriers in using digital technology. Most concerning is the inability of providers to practice across state lines. Licensing limitations effectively prohibit clinicians working on clinical trials from recruiting patients from outside the state where the clinician is licensed, thereby diminishing the impact of the federal changes aimed at decentralizing clinical trials. This is especially important for rare diseases affecting fewer than 200,000 people in the United States, for which utilizing clinical trials across state lines may significantly increase the likelihood of a successful and diverse clinical trial.

While this is ultimately a state issue, non-binding guidance from the FDA to states on how to bolster clinical trial modernization through licensure flexibilities would help catalyze change at the state level. Our recommendation is to include language in Section 502 requiring the FDA to set up an intergovernmental working group with state and federal regulators to develop such guidance. This group will likely identify other areas beyond licensing that may need to be addressed, such as mailing of non-approved medications.

If the *PREVENT Pandemics Act* aims to facilitate international harmonization between FDA and foreign regulators with respect to the use of digital health technologies in clinical trials, we are hopeful that the Committee agrees it is also important to promote harmonization between state and federal regulators within the United States.

Thank you for your consideration of this important request.

Sincerely,

Alliance for Connected Care
ALS Association
American Academy of Neurology

American Parkinson Disease Association
Ascension
Cancer Support Community
Coalition for Headache and Migraine Patients
Columbia University Irving Medical Center
Dallas Area Parkinson Society
Davis Phinney Foundation for Parkinson’s
Friends of Parkinson's Inc.
Johns Hopkins Medicine
National Multiple Sclerosis Society
The Michael J. Fox Foundation for Parkinson’s Research
The Parkinson Alliance
The Parkinson’s Unity Walk
Wisconsin Parkinson Association