November 15, 2021

The Honorable Patty Murray
Chairwoman
Senate Committee on Health
Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Senate Committee on Health
Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Neal
Chairman
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairs Murray, Neal, and Pallone and Ranking Members Burr, Brady, and McMorris Rodgers:

The undersigned organizations represent millions of patients, health care providers, and advocates for health equity who are deeply committed to improving our science base through the adequate representation of underrepresented communities in vital medical research. We strongly support passage of the Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act (H.R. 5030/S. 2706) and urge you to prioritize this bill in your Committees to ensure it is enacted into law this year. The DIVERSE Trials Act would make it easier for all patients to participate in clinical trials while removing barriers that are known to keep certain racial and ethnic groups, older adults, rural residents, and those with limited incomes from being appropriately represented. This legislation has earned bipartisan, bicameral support, takes a practical approach that will lead to near-term improvements, and entails little cost to taxpayers. The three provisions of the DIVERSE Trials Act will result in more efficient, inclusive, and accessible research, which will benefit the health of all Americans:

First, the legislation would permit individuals to receive financial support for the non-medical costs associated with their participation in clinical trials, by creating a statutory safe harbor for clinical trial sponsors to use in reimbursing such costs. Today, clinical trial sponsors generally supply without charge the drug or technology being investigated while insurers generally cover the other treatment costs associated with a trial. Often, however, patients must pay non-medical costs associated with participating in a clinical trial—such as transportation to a trial site, lodging in another city, meals, and additional childcare. For many people, these costs are difficult to bear and may be the difference between saying “yes” or “no” to a clinical trial that could improve their own care and the care of others suffering from the same disease. For example, a recent study showed that patients making less than
$50,000 a year are 30 percent less likely to enroll in a cancer clinical trial.¹ Financial barriers are a major barrier for communities underrepresented in clinical trials resulting in trials that do not adequately represent the patient populations who are intended to use the treatments being studied. By clarifying that trial sponsors can financially support patients’ non-medical costs, the DIVERSE Trials Act can change this reality for the better.

**Second, the DIVERSE Trials Act would allow trial sponsors to provide individuals with the technology necessary for them to participate remotely in clinical trials.** Clinical trials almost always require participants to report their condition, symptoms, side effects, or other data on a regular basis and/or to have certain health indicators monitored by web-enabled technology. Some trials of new treatments consist entirely or substantially of such monitoring and so lend themselves to more comfortable and efficient remote participation. For this to work, however, participants must have access to technologies, such as portable computers, tablets, and software applications. This legislation would take the common-sense step of allowing sponsors to provide such technology to participants in a clinical trial. The benefits of this provision include eliminating a financial barrier to participation in clinical trials that are increasingly incorporating web-enabled technology and fostering the conduct of trials that utilize remote participation and include larger cohorts of underrepresented groups.

**Finally, the legislation would require the Department of Health and Human Services (HHS) to issue guidance on decentralized clinical trials.** While the COVID-19 pandemic accelerated the need for clinical trials in which patients could participate at or close to home, researchers have long endeavored to make clinical trials more convenient for participants. The decentralized approach could open the door to clinical trials for a much broader array of participants, such as those who live hours from a trial site or do not have the ability to make repeated visits to the trial site due to work or caregiving schedules. A significant hinderance to the conduct of decentralized trials has been the absence of clear guidance on the design, conduct, oversight, and other requirements of this research approach. Issuing guidance on the conduct of decentralized clinical trials is an urgent priority for patients, advocates, and health care researchers alike.

We stand at the cusp of a health care revolution—as breakthroughs in genetics, immunotherapy, systems biology, precision medicine, and other specialties lead to more effective treatments and even potential cures for many of the most intractable diseases. Clinical trials are the means by which such breakthroughs are shown to be effective and safe. Making clinical trials more efficient, inclusive, and accessible—as the DIVERSE Trials Act would do—means bringing the growing benefits of medicine and science closer to every American.

**Please prioritize the DIVERSE Trials Act (H.R. 5030/ S. 2706) this year to ensure more patients—regardless of their race, ethnicity, economic means, or geographic location—have a chance to enroll in clinical trials.**

Sincerely,

Abramson Cancer Center at Penn Medicine
Academy of Oncology Nurse & Patient Navigators (AONN)
Active Surveillance Patients international
ADAP Advocacy Association

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Adult Congenital Heart Association
Aimed Alliance
ALK Positive Inc.
Alliance for Aging Research
ALPHA-1 FOUNDATION
American Association for Cancer Research
American Cancer Society Cancer Action Network
American Heart Association
American Liver Foundation
American Lung Association
American Muslim Health Professionals (AMHP)
American Society for Radiation Oncology
American Urological Association
Answer Cancer Foundation
Arthritis Foundation
Asian & Pacific Islander American Health Form
Association for Clinical Oncology
Association of American Cancer Institutes
Association of Black Cardiologists
Association of Community Cancer Centers (ACCC)
Association of Oncology Social Work
Association of Women in Rheumatology
Asthma and Allergy Foundation of America
Autoimmune Association
BlackDoctor, Inc
Breastcancer.org
Cancer Action Coalition of Virginia
Cancer and Careers
Cancer Support Community
CANCER101
CancerCare
Caregiver Action Network
Children’s Cancer Cause
Cholangiocarcinoma Foundation
CLL Society
Color of Crohn’s & Chronic Illness
Colorectal Cancer Alliance
Community Access National Network (CANN)
Crohn’s & Colitis Foundation
Deadliest Cancers Coalition
Debbie’s Dream Foundation: Curing Stomach Cancer
Depression and Bipolar Support Alliance
Digestive Disease National Coalition
Digestive Health Physicians Association (DHPA)
Diverse Health Hub
Epilepsy Foundation
EveryLife Foundation for Rare Diseases
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Friends of Cancer Research
Global Healthy Living Foundation
Global Liver Institute
GO2 Foundation for Lung Cancer
GRASP
Head and Neck Cancer Alliance
HealthTree Foundation
Healthy Americas Foundation
HealthyWomen
Heart Valve Voice US
Hemophilia Federation of America
Hep B United
Hepatitis B Foundation
Hispanic Health Network
HISPANIC HEALTHCARE TASK FORCE
HIV + Hepatitis Policy Institute
Hope for Stomach Cancer
ICAN, International Cancer Advocacy Network
Infinite Strength, Inc.
Infusion Access Foundation (IAF)
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
JDRF
KidneyCAN
KRAS Kickers
Latino Commission on AIDS
Lazarex Cancer Foundation
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Male Breast Cancer Coalition
Malecare Cancer Support
Metastatic Breast Cancer Network
Moffitt Cancer Center
Multiple Sclerosis Association of America
Muscular Dystrophy Association
Musella Foundation For Brain Tumor Research & Information, Inc
National Alliance for Hispanic Health
National Alliance of State Prostate Cancer Coalitions
National Association of Nutrition and Aging Services Programs
National Black Nurses Association
National Brain Tumor Society
National Cancer Registrars Association
National Comprehensive Cancer Network
National Eczema Association
National Health Council
National Hispanic Cancer Awareness Day
National Hispanic Council on Aging
National Hispanic Medical Association
National Infusion Center Association (NICA)
National LGBT Cancer Project
National Marrow Donor Program/Be The Match
National Medical Association
National Minority Quality Forum
National MS Society
National Patient Advocate Foundation
National Rural Health Association
National Urban League
NCODA
Oncology Nursing Society
Oral Cancer Foundation
Ovarian Cancer Research Alliance
Pancreatic Cancer Action Network
Patient Advocates In Research (PAIR)
Patient Empowerment Network
Patients Rising
Pennsylvania Prostate Cancer Coalition (PPCC)
Phelan-McDermid Syndrome Foundation
PlusInc
Preparedness and Treatment Equity Coalition
Prevent Blindness
Preventive Cardiovascular Nurses Association
Prostate Cancer International
Prostate Conditions Education Council
Qmetrics Technologies
Research Advocacy Network
RetireSafe
Research!America
Scleroderma Research Foundation
Skin of Color Society
Society for Women's Health Research
Solve M.E.
Spondylitis Association of America
Stand Up To Cancer
Susan G. Komen
THANC (Thyroid, Head and Neck Cancer) Foundation
The EndBrainCancer Initiative (EBCI) (formerly the Chris Elliott Fund)
The Gerontological Society of America
The Kennedy Forum
The Leukemia & Lymphoma Society
The Mended Hearts, Inc
The Multiple Myeloma Research Foundation (MMRF)
The Prostate Health Education Network PHEN
Tigerlily Foundation
Triage Cancer
TSC Alliance
Twisted Pink
U.S. Pain Foundation
UsAgainstAlzheimer's
USC Norris Comprehensive Cancer Center
Vaccinate Your Family
WomenHeart: The National Coalition for Women with Heart Disease
Young Survival Coalition
ZERO - The End of Prostate Cancer

CC: The Honorable Robert Menendez
    The Honorable Tim Scott
    The Honorable Raul Ruiz
    The Honorable Larry Bucshon