ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

March 17, 2022

The Honorable Anna Eshoo
Chairwoman, House Energy & Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member, House Energy & Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

RE: House Energy and Commerce Subcommittee on Health Hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight."

Dear Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Subcommittee,

The Association of Clinical Research Organizations (ACRO) appreciates the opportunity to submit this statement for the record for the Subcommittee's hearing, "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight."

ACRO represents the world's leading clinical research and technology organizations. ACRO and its members advocate on a global basis for safe, ethical, high-quality medical research so that patients can benefit from the timely development of new treatments and therapies. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics, and medical devices—from pre-clinical, proof of concept, and first-in-man studies through post-approval and pharmacovigilance research. With more than 200,000 employees engaged in research activities in 114 countries, ACRO member companies manage or otherwise support a majority of all FDA-regulated clinical investigations worldwide.

The COVID-19 pandemic presented a significant challenge to the clinical research industry, but thanks in large part to the work ACRO member companies have been doing for the past 20 years as part of the Association—and through valued partnerships with policymakers, regulators, and other stakeholders—ACRO members were able to meet the challenge head on and help to develop multiple vaccines in record time.

ACRO appreciates all the hard work the Subcommittee has done in preparation for today's hearing. ACRO and its members have spent the better part of the past two years focused on advancing diversity and inclusion in clinical research and advancing the adoption of decentralized clinical trials (DCTs)—two issues we are pleased to see be included in many of the bills being considered in today's hearing.

Improving Diversity and Inclusion in Clinical Research

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ACRO is extremely supportive of the work Congress is doing to bolster diversity and inclusion in clinical research, not only among participants but throughout the research workforce. ACRO and its members are focused on a multitude of issues to be addressed to make our vision of a truly representative clinical research ecosystem a reality. We need to ensure that we are supporting robust clinical trial networks and that research is being conducted in the communities of the patients we're hoping to reach. We need to improve awareness and access so that historically excluded populations know that clinical research opportunities are available to them. We must solve issues regarding data completeness and granularity to be confident that we are enrolling the right trials into the right patients. Additionally, we will need to tackle global harmonization efforts so that trials are able to run smoothly around the world.

ACRO's Committee on Diversity & Inclusion in Clinical Trials has developed a Statement of Principles to guide the work our members do to make meaningful improvements in the representativeness of clinical trials. The statement includes the following four pillars:

- Improving Health Equity Through Access to Trials
    - Increase awareness and opportunities for clinical trial participation among diverse populations
    - Reduce the burden of participation for diverse communities through innovative methodologies, decentralized trial support services, and digital technologies
    - Work with predominantly underrepresented communities to build trust between stakeholders
- Empowering Research Partners (Patients, Sites, Health Care Providers)
    - Educate and engage patients as research partners throughout the clinical development lifecycle
    - Harness data to better characterize relevant patient populations
    - Support sites with training and culturally relevant materials to work with diverse communities
    - Use data to identify investigators with access to clinically relevant, diverse patients
- Partnering with Stakeholders & Policymakers
    - Work with policymakers and regulators around the world to promote policies that improve diversity and inclusion of underrepresented study participants
    - Embed a patient-centric mindset in policy recommendations by partnering with patient and minority advocacy groups
    - Collaborate with other industry groups to drive progress towards inclusive clinical trials
- Driving Workforce Diversity, Equity, & Inclusion
    - Support programs that drive diversity and inclusion in the clinical research industry workforce including employee retention, recruitment, and development

- Foster relationships with minority healthcare associations and other groups to bring new generations into clinical research

ACRO sees the meaningful work of improving diversity and inclusion in clinical research as a collaborative effort that requires participation from a broad group of stakeholders. We encourage Congress to continue its important work on this front, especially through many of the bills up for consideration today, and to ensure the inclusion of these groups—clinical research organizations, technology providers, sponsors, sites, patients, etc.—in diversity and inclusion initiatives going forward.

Driving the Adoption of Decentralized Clinical Trials

ACRO appreciates Congress' focus on improving adoption of decentralized clinical trials (DCTs). The ability to decentralize pieces of the clinical research process, to really bring the trial to the patient, is a tremendous step forward in the modernization of clinical research. These decentralized elements will allow us to reach more patients than ever before and aid in our goal of improving diversity and inclusion, not just racial diversity but geographical as well. We should be mindful not to assume that DCTs are a quick fix to struggles regarding inclusion, as will may face hurdles such as access to and understanding of technology, but it is certainly a step in the right direction. To make this adoption possible it is important that we gain clarity from regulators around the acceptance of these DCT elements so that clinical trial sponsors can have confidence including them in protocols going forward.

ACRO's Decentralized Clinical Trials Working Party was formed in 2019 to examine the barriers to adoption of DCTs and create quality-based principles and tools to facilitate implementation of DCTs. With the onset of the COVID-19 pandemic in 2020, the work of ACRO's DCT Working Party became even more important to ensuring that trials continued to run, and that patients and regulators could have confidence in both the safety and data integrity of clinical research through the pandemic.

As part of the DCT Working Party's work, the team developed a series of Data Flow Maps to build confidence and trust in DCTs by providing transparency and visibility into data flow, data controls, and data traceability with a DCT to illustrate how a decentralized model guards data quality and integrity. The Data Flow Maps address eConsent, Direct-to-Patient Shipping, Investigator-Participant Interactions, Connected Devices, and Home Health Visits.[1] Below you will see the Connected Devices Data Flow Map that outlines how data collected from wearable devices moves through the trial.

[1] All of ACRO's DCT resources can be found here.

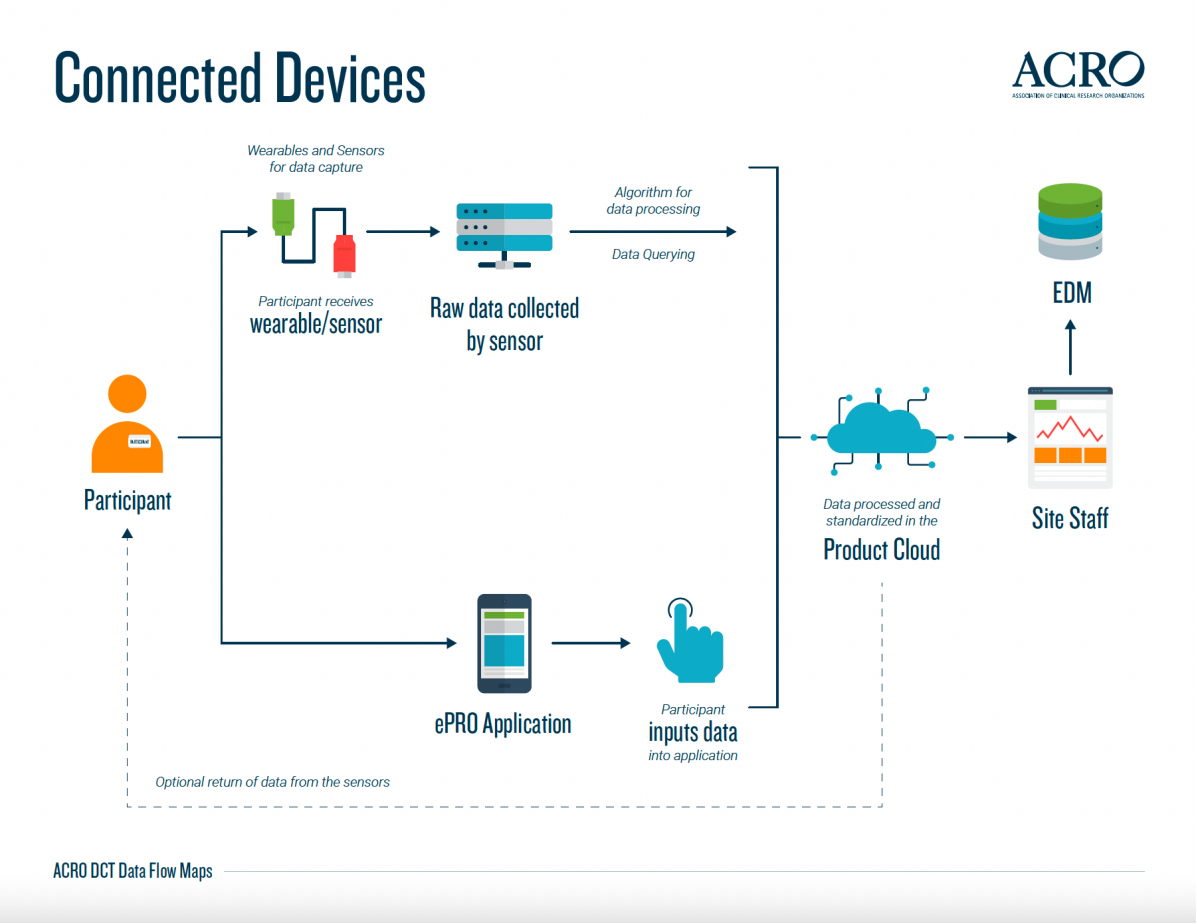

Figure 1. Connected Devices data flow map as developed by ACRO's Decentralized Clinical Trials Working Party. Participant enrolls into trial and receives connected devices in the form of the wearables/sensors for data capture and/or the electronic patient reported outcomes (ePRO) application (on a personal or provisional device). Raw data collected by the wearables/sensors are queried using the algorithm for data processing, and later the data are processed and standardized in the product cloud. The data input by the participant into ePRO is also processed and standardized in the product cloud. From here, the data on ePRO inputs and wearables/sensors are directed to site staff, and later into the electronic data management (EDM) system.

Conclusion

ACRO would like to thank the Subcommittee for the opportunity to provide this statement for the record for this important hearing. We appreciate your leadership and look forward to working with you further on these issues.

Sincerely,

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