ACRO Innovate Advocate Collaborate

May 9, 2025

Statement for the Record
United States Senate Committee on Appropriations Hearing
Biomedical Research: Keeping America's Edge in Innovation

The Honorable Senator Susan Collins
Chair, Senate Appropriations Committee
Room S-128, The Capitol
Washington, DC 20510

The Honorable Senator Patty Murray
Vice Chair, Senate Appropriations Committee
Room S-128, The Capitol
Washington, DC 20510

Chair Collins, Vice Chair Murray, and Members of the Senate Appropriations Committee:

The Association of Clinical Research Organizations (ACRO) thanks the Committee for holding the hearing entitled "Biomedical Research: Keeping America's Edge in Innovation" on April 30, 2025. Ensuring that the country's scientific and medical research apparatus is robustly funded is paramount to the United States remaining the world leader in biomedical innovation and we are pleased to see the Committee prioritizing this issue.

ACRO, founded in 2002, is non-profit trade association representing the world's leading clinical research and technology organizations, which provide specialized services that are integral to the development of drugs, biologics and medical devices that enable patients to live longer, healthier, and more productive lives. ACRO members provide a wide range of specialized services across the entire spectrum of development—from pre-clinical, proof of concept, and first in human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies employ nearly 400,000 people worldwide and conduct research in every global region.

While the April 30 hearing was focused on *medical product* innovation, it is imperative to note that an essential concomitant to medical product innovation is *regulatory* innovation. Regulators around the globe are grappling with the complex challenges of designing regulatory regimes for an ever-changing world. Thanks to the innovation the U.S. has fostered these past decades, the Food and Drug Administration (FDA/the Agency) has been seen as the global leader in drug development oversight. The Agency's scientific expertise and leadership have enabled it to blaze a globally influential path by issuing guidance documents that are forward-leaning, pragmatic, and flexible, cementing its gold standard reputation around the world, and ensuring the safety and efficacy of new biomedical products while encouraging the availability of new drugs and new treatments for the patients who need them.

Due to this aforementioned boon in U.S. innovation, 100% of ACRO's members are developing and/or utilizing artificial intelligence to streamline the drug development process and bring safe and effective treatments to patients sooner than ever before. More than three-quarters of ACRO members are using AI to streamline data management, while over 60% are using it for study start-up, and over 50% are using it to help with investigator and patient recruitment and retention—notoriously one of the longest processes in drug development.

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ACRO members, and other industry stakeholders like biopharmaceutical sponsors and patients, rely on adequate funding of the Agency, which supports scientific expertise as well as regulatory stability and certainty. This helps to guide portfolio prioritization and capital investment.

ACRO members employ over 125,000 people in the United States and worked on almost 9,000 clinical trials in 2024. That breaks down into 4,367 unique compounds, 1,396 rare and orphan disease trials, and 822 pediatric trials, bringing in almost $100 billion in revenue. Clinical research has been able to thrive in the U.S. due to relative regulatory stability up to this point.

But since April 1st FDA staff has been reduced by over 20%. These changes to FDA's personnel have threatened to undermine the stability relied upon by patients and industry. As Dr. Esham mentioned in her opening statement, there were 14,870 active commercial and research investigational new drug programs at the Center for Drug Evaluation and Research (CDER) in 2024. FDA requires robust funding and expert staff in order to be able to keep pace with innovation in the clinical research industry. If this funding is cut, review timelines will inevitably get longer, the U.S. will become a less attractive place to do research and launch new medicines, economic output will decrease, and patients will lose out on lifesaving treatments.

While ACRO members are largely focused on drug development specifically, and therefore the operations of FDA, the importance of federal funding in early phase discovery and development cannot be overlooked. As Chair Collins stated in her opening remarks, FDA has approved more than 600 cancer treatments in the last 20 years, all of which were made possible by decades of investments in basic research made by the National Cancer Institute (NCI). And it's not just NCI. The National Science Foundation, additional Centers within the National Institutes of Health, and other federal agencies have invested countless billions of dollars into research that has led to the treatments and cures many people have access to today. If this early phase research goes unfunded, clinical trials will stop, treatments will not get to patients, and the U.S. will cease to be the global leader in biomedical innovation.

Again, we thank the Committee for holding this important hearing and giving us the opportunity to submit a statement for the record. ACRO and its members believe robust funding for the research enterprise is essential for patients, progress, and America's ability to lead into the next frontier of drug development.

Sincerely,

Doug Peddicord, Ph.D.
Executive Director