ACRO Innovate Advocate Collaborate

June 30, 2026

Congressman Jake Auchincloss (D-MA-04)
1524 Longworth House Office Building
Washington, DC 20515

ACRO Comment re: Next-Generation U.S. Clinical Development to Accelerate Cures Draft

Founded in 2001, the Association of Clinical Research Organizations (ACRO) is a 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 drug development—from preclinical, proof of concept, and first in human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies employ more than 470,000 people worldwide and conduct research in every global region.

General Comments

ACRO thanks the Congressman for kicking off this effort and is supportive of the steps taken in this legislative summary to move toward clinical trial modernization and improved access to new therapies.

In all areas of this legislation, ACRO encourages the consideration of clinical research organizations (CROs) and clinical technology organizations (CTOs) as system-level partners and enablers for success in clinical research innovation. ACRO members operate at the intersection of sponsors, health systems, regulators, and patients, and already deliver many of the capabilities the proposal seeks to scale: multi-site coordination, regulatory-grade data governance, ethical oversight, early-phase trial execution, and global quality systems. Therefore, recognizing CROs and CTOs as crucial partners to FDA, Congress, and other global regulatory bodies, rather than as service arms, would improve the effectiveness, scalability, and durability of the initiatives outlined in this discussion draft.

Section Specific Comments

Sections 2-4: Cures in Care Initiative (CCI), Point-of Care Infrastructure, and Implementing & Scaling Point-of-Care Platforms

ACRO is supportive of the expansion of point-of-care trials as they have the potential to improve participant access to research, thereby increasing patient recruitment in the US and improving representativeness in clinical trials. As the FDA noted in its 2024 guidance on the topic, "Leveraging established health care institutions and existing clinical expertise in the medical community can reduce startup times and speed up enrollment." We would caution against using NIH and ARPA-H as the implementing bodies alone for the platform pilots mentioned in Sec. 4, as this will likely exacerbate existing structural problems. Productive clinical trial sites and site networks already exist and perform high-quality research efficiently for industry sponsors, partnering with CROs and CTOs to find and recruit patients.

The most effective path forward for a pilot such as what is being proposed in this draft would be to leverage existing site infrastructure, and CRO & CTO executional capabilities rather than investing in the creation of new, federally managed networks. Startup timelines at AMCs consistently rank among the longest in the clinical trial ecosystem, and most US patients do not receive care at AMCs but instead at local community practices. Keeping NIH and ARPA-H in a management position of these pilots would require structural changes that would add additional costs and time.

A robust ecosystem of research-ready sites already operates in a "warm base" state, supported by the combined capabilities of ACRO's CRO and CTO members. Together, these organizations provide platforms that provide end-to-end operational delivery, including rapid site activation, performance-based enrollment management, and integrated data systems. These capabilities enable studies to be launched and scaled quickly, with predictable timelines and accountability mechanisms that are difficult to replicate in newly established networks.

Experience from recent federal initiatives (e.g., the NIH CoVPN and ACTIV trials) underscores that building or coordinating new networks can introduce delays, duplication, and fragmented execution. In contrast, CROs are purpose-built to operationalize trials at scale, with established technology and site partnerships, real-time performance oversight, and the ability to dynamically allocate resources to meet enrollment targets. By aligning federal investment with this existing infrastructure, rather than reinventing the wheel, we can accelerate the deployment of point-of-care trial models, reduce time to evidence generation, and ensure more efficient use of public resources. The most successful model for this pilot would be partnerships between AMCs, community hospitals, independent research sites, clinical research organizations, and clinical technology companies to leverage the strengths that each entity brings to the table to solve our current access and recruitment challenges. These entities are best placed to handle the implementation of the pilot, while NIH and ARPA-H would be better suited to provide scientific and regulatory support along the way.

Given the existing role that CROs play in the clinical research ecosystem and the opportunity to collaborate with CROs on this CCI initiative, ACRO encourages this legislation to also designate CROs as eligible platform operators and integrators within this program. This would provide CROs with the authorization to operate (or co-operate) reusable point-of-care trial platforms, provide standardized operating models, quality systems, and governance, and lead onboarding, workforce training, and technical enablement for sites, which will be largely beneficial for community and rural sites and safety-net care providers.

With regard to real-world data as mentioned in Section 3, ACRO member neutrality builds trust across sponsors and health systems, and CRO data governance capabilities help ensure consistency, auditability, and regulatory confidence in RWD. We would recommend that CROs are designated as neutral RWD stewards and interoperability integrators. CROs should be recognized as independent operators of regulatory-grade RWD pipelines, connectors between EHR systems, sponsors, and regulators, and managers of AI-enabled monitoring, validations, and data quality assurance.

Section 5: New Approach Methodologies (NAMs) in Preclinical and Early Clinical Development

ACRO is supportive of the efforts to incorporate New Approach Methodologies (NAMs) into preclinical development and early phase trials outlined in this section. However, ACRO recommends adding language that lists CROs as collaborators with federal partners on NAMs incorporation. When thinking

about expediting the preclinical investment to IND timeline, NAMs represent the largest potential for acceleration as they can better predict human safety and efficacy. Incorporating NAMs into non-clinical data packages would reduce overall IND timelines and non-clinical study costs.

ACRO supports FDA's recent guidance on NAMs. FDA leads the utilization of NAMs in regulatory submissions, and existing Agency guidance on NAMs is continuing to stimulate investment. The US should lead other global regulators when it comes to incorporating promising NAMs into research initiatives to expedite validation. To continue US leadership in NAMs usage, ACRO recommends the following additions to this section:

- ACRO strongly recommends that this legislation includes CROs as partners on FDA collaboration in order to leverage lessons learned from pre-competitive collaboration of NAMs incorporation. ACRO also recommends that this legislation look to authorize CROs to serve as NAM validation and translation hubs, therefore allowing CROs to aggregate validation data sets across platforms, translate NAM evidence into regulatory submissions and guidance, and convene pre-competitive consortia across sponsors and technology developers.
- ACRO suggests that this legislation include instructions requiring FDA to release expectations for NAM validation/qualification in supporting specific context of use (e.g., ISTAND).
- In reference to this point in the discussion draft - "Instructs FDA to issue guidance and regulatory frameworks to further adoption of in vitro and in silico technologies to enhance preclinical and early clinical research through determining lead use cases, detailing data needed for validation, identifying pathways for validation to support rare disease therapeutics and advancing efforts to reduce animal testing," ACRO asks that the Congressman instruct FDA to provide input on development and modification of thresholds for when animal testing can be reduced or eliminated.

Section 6: Modernized Phase I Trial Oversight

ACRO supports the Congressman's efforts to spur Phase I activity in the US. A number of recommendations to be considered include:

- More consistent use and enforcement of single IRBs for multi-site first-in-human trials, paired with clearer expectations for timelines.
    - Urge OMB to release the sIRB final rule
        - Implementation of this FDA rule would require that a single IRB be used for any multi-site FDA regulated PI clinical investigations. In addition, it would help to normalize the use of single IRBs for PI clinical investigations that are being conducted at only one site.
    - Create a national fast track framework for Phase I startup. Standardizing contracting, IRB review, and site activation processes could significantly reduce startup delays and improve operational predictability. One practical starting point could be a public-private partnership, coordinated across FDA, NIH, HHS broadly, and industry stakeholders (IRBs, CROs, CTOs, sponsors, patient groups, etc.) to establish a network of qualified Phase I sites operating with standardized startup processes, centralized IRB review, common operational metrics, and accelerated activation targets.
    - Work with outside stakeholders mentioned above to develop FIH-specific informed consent templates to reduce variability and rework at the site level.
    - Better alignment of IRB and DSMB/safety review timelines through centralized or parallel review models. FDA should publish risk-based criteria for when full interim DMC

oversight is required vs. lighter-touch monitoring (e.g., safety officer reviews, scheduled safety checkpoints). We see continued confusion re: what is required to be reported to IRBs, and FDA guidance is not aligned on this. Submitting single events, with no real safety signal, can lead to unnecessary amendments and unanticipated problem determinations, which further impacts timelines.

- Move toward a risk-tiered, adaptive regulatory framework for FIH trials.
    - Current processes often apply a one size fits all approach to early-phase studies. A more tailored model could include:
        - A risk-tiered IND pathway with clear, objective criteria for different categories of FIH trials. Establish clear review target timelines (e.g., 15-21 business days) for safety/efficacy focused Phase I submissions, provide dedicated FDA review teams, and offer rapid INTERACT/Pre-IND consult spots.
        - Greater flexibility for adaptive designs and dose escalation, including options like rolling review for lower-risk cohorts.
        - Streamlined expectations for safety reporting and protocol modifications in early-phase contexts (e.g., expand adaptive and model-informed approaches in early development. FDA could further encourage adaptive trial designs and model-informed development approaches to support faster evidence-based go/no go decisions while maintaining safety and data integrity standards.
        - This is an area where additional industry input and transparency would be critical.
- Modernize expectations re: AI-enabled trial execution.
    - Part of the reason Phase I is moving offshore is because of lower operating costs and faster enrollment timelines. While FDA cannot directly address underlying labor economics, it can help improve US competitiveness by reducing uncertainty around adoption of AI-enabled operational technologies that have the potential to lower development costs and improve execution speed. Clearer implementation guidance around AI use in feasibility, protocol optimization, enrollment forecasting, patient engagement, operational monitoring, and real-time analytics could help sponsors more confidently modernize Phase I operations in the U.S. There may also be a role for HHS and NIST in helping to establish interoperability, validation, and trustworthy AI implementation standards for clinical research.

ACRO also suggests the Congressman review recent efforts from HHS/FDA regarding Operation TrialBlazer. A number of initiatives under the Operation TrialBlazer umbrella would help to speed time to IND and Phase I trials. For example, the 30-day IND review clock is generally not the real bottleneck in the process. Delays typically occur during pre-submission (CMC readiness) and post-safe to proceed (amendments without timelines). ACRO recommends that the Congressman aligns with FDA's Expedited IND Pilot Program, which targets these issues through rolling pre-submission review. This differs from Australia's CTN model, where authorization is ethics committee, not regulator, led. We urge Congress to ensure that HHS, and FDA more specifically, are properly funded and resourced to guarantee we make progress on these steps to speed innovation in the US.

Section 7: Global Regulatory Alignment

ACRO supports the actions outlined in Section 7 to ensure global harmonization of clinical research practices and health technologies. Differing priorities across countries prevent seamless clinical

research practices and global harmonization. ACRO encourages the Congressman to leverage CROs and CTOs as global harmonizers and utilize the unique positions they hold in the global clinical research industry.

It is vital for FDA to continue active participation and leadership within pivotal, existing harmonization-focused organizations, such as the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICMRA is a professional society for heads of global regulatory authorities and pursues key initiatives like harmonization efforts and the continuity of research during public health emergencies, such as the COVID-19 pandemic. ICH brings together regulatory authorities and the pharmaceutical industry to discuss the scientific and technical aspects of pharmaceutical development. ICH primarily issues draft guidelines on key clinical research topics such as Good Clinical Practice (GCP). Fortunately, FDA has a strong, recognized history of leadership within ICH. This must continue and should be bolstered by the initiatives provided in this section of the resulting legislation. ACRO has long shared recommendations with FDA and ICH on global harmonization initiatives, including ICH E20: Adaptive Designs for Clinical Trials (2025), and has worked to interpret ICH Good Clinical Practice guidelines for industry – Thought Leadership on ICH E6(R3).

Legislative language rooted in the proposals from this section should also focus on how global harmonization will promote US competitiveness while still maintaining US flexibility. ACRO supports initiatives that will allow the US to preserve its leadership in drug development, such as through the enhanced inspection and data quality verification initiatives outlined in the discussion draft.

Section 8: Adequate U.S. Representation in Clinical Trials

ACRO strongly supports ensuring adequate US representation in clinical trials. Promoting representation and equity in clinical trials and supporting opportunities to diversify participant populations are cornerstones of ACRO's advocacy.

While ensuring adequate representation of Americans in clinical trials is important, so too is ensuring that the data collected in the US is representative of the intended treatment population within the country. Provisions to bolster participation among historically underrepresented populations in clinical research (e.g., cost-sharing assistance, reimbursement for travel expenses, the provision of DHTs, and removing patient stipends from taxable income) would help to ensure scientific quality of data and would also help to speed recruitment. Provisions like these should be considered in any legislative package taking such a holistic view of clinical trial modernization.

On the discussion draft point "Establishes a requirement for clinical data to be collected in the US, with exceptions reviewed by the HHS Secretary for GCP compliance and applicability of the data to the US health care system," ACRO would like to clarify the intention behind this and understand how this requirement would impact the collection and use of foreign clinical trial data. Clinical research is, and should remain, an international industry that relies on data collected from patients and researchers worldwide. We look to learn how this point would be put into practice and strongly recommend that it not lead to a US-exclusive approach to clinical research and avoid a broad geographic data collection mandate. ACRO also strongly opposes FDA setting specific percentage thresholds of data from trials that should come from US patients. Percentages for therapeutic area representation are very specific; details regarding how the science and data behind the set percentages will be managed and updated should be included.

Finally, ACRO asks that additional clarification be provided on the second point in this section, "Calls for patients in the US to be enrolled in a multinational platform trial." What is the intention behind calling for patient enrollment in a multinational platform trial and what may a practical application of this look like? Instituting a broad requirement for US-collected data can also affect multinational trial design and slow down patient enrollment. This requirement and its impacts on patients enrolling in multinational platform trials should be reconciled with ICH principles.

Section 9: Rare Disease and Public Engagement

ACRO supports the efforts provided in this section to enhance rare disease research, guidance, and public engagement. FDA's Rare Disease Innovation Hub (RDIH) has yet to be codified and remains under-resourced. ACRO supports the codification and allocation of additional resources for the RDIH in order to improve operation of rare disease platform trials, support natural history studies and outcome measure validation, and to facilitate early and consistent FDA-sponsor engagement.

Furthermore, given ACRO members' insights across the clinical trial ecosystem, ACRO encourages the Congressman to consider the role of CROs and CTOs in rare disease research and urges collaboration between CROs, CTOs, FDA Centers, and other partners in support of rare disease treatments. ACRO members have robust resources in place to aide in the identification and recruitment of patients into rare disease research.

Conclusion

ACRO thanks the Congressman for this opportunity to comment on the Next-Generation U.S. Clinical Development to Accelerate Cures legislative summary and we look forward to continued collaboration on this effort. The proposed modernization of U.S. clinical development presents a generational opportunity. Its success will depend not only on policy reform, but on executional partners with proven capacity to operate at scale**.**

Explicit recognition of CROs and CTOs as trusted, system level enablers across CCI platforms, Phase 1 oversight, real-world data infrastructure, and global alignment would significantly strengthen the proposal's impact, speed, and sustainability.

Please do not hesitate to contact ACRO if we can provide further details or answer any questions (smcleod@acrohealth.org).

Respectfully,

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