June 30, 2026

The Honorable Jake Auchincloss
US House of Representatives
Washington, DC 20515

Re: Legislative Discussion Draft of the Next-Generation US Clinical Development to Accelerate Cures

Dear Representative Auchincloss:

On behalf of the FasterCures team at the Milken Institute, thank you for your leadership on clinical trial modernization and for the opportunity to comment on the discussion draft of the Next-Generation US Clinical Development to Accelerate Cures.

For more than two decades, FasterCures has worked to accelerate the translation of biomedical discoveries into treatments that reach patients more quickly. Since 2020, we have focused deeply on clinical research innovation and infrastructure, prompted by the challenges the US experienced during the COVID-19 pandemic running clinical trials across the country in the context of a public health emergency:

- We published a series of reports on *Lessons Learned from COVID-19* for the biomedical innovation ecosystem, including about clinical trial infrastructure and conduct.
- We were invited to lead the Infrastructure Working Group for Operation Warp Speed's lessons learned on the clinical evaluation of therapeutics during the pandemic.
- We launched an initiative to support the growth of more community-based research infrastructure, publishing recommendations for the public and private sectors.
- These reports led to the creation of the ENRICH-CT multi-stakeholder coalition (more on that below).
- Most recently, our report on *The Future of Biomedical Research and Innovation* included six sets of recommendations to preserve and strengthen US leadership in the life sciences, including recommendations for strengthening the clinical trials enterprise.
- I have played a leadership role on the National Academies Clinical Trials 2030 initiative, the Clinical Trials Transformation Initiative's Executive Committee, and serve on the boards of the Duke Margolis Institute for Health and Protas.

We currently lead several active workstreams that address strengthening clinical trials infrastructure and access:

- **Enabling Networks of Research Infrastructure for Community Health Through Clinical Trials (ENRICH-CT):** A multistakeholder initiative with more than 90 member organizations—representing government agencies, industry, health systems, EHR and technology vendors, community-based organizations, and more—focused on driving dialogue and advancing practical solutions for the public and private sectors to support infrastructure in the US for more community-based clinical research;
- **Democratizing Access to Clinical Research:** Explores strategies for democratizing access to clinical research, centering new players, nontraditional partners, and new platforms and systems that can make research accessible to all; and
- **Representation in Clinical Trials:** Aims to develop strategies and policies to increase representation at all stages of clinical research.

Additionally, in 2025, the Milken Institute consulted and convened nearly 100 leaders across science, industry, government, and patient communities to examine The Future of US Biomedical Research and Innovation, producing a set of recommendations to sustain US leadership in life sciences, many related to clinical research conduct and infrastructure.

Over the course of more than a year, a working group of cross-sector experts from our ENRICH-CT coalition prioritized areas for near- and long-term action to bring research closer to communities, falling under the broad headings of **making trials more patient-centric** and **embedding research in health care.** These recommendations will be published in a report this summer and, along with the other initiatives I just described, inform our comments below.

Our efforts point to the same conclusion that animates your proposal: Clinical trials remain one of the most significant bottlenecks between scientific discovery and patient impact. More than 80 percent of trials are delayed or fail to launch altogether due to insufficient enrollment, and the large majority of Americans, particularly those served by community health systems and rural providers, have no meaningful path into clinical research where they actually receive care. We will not be able to realize the significant scientific promise that currently exists, or maintain US leadership in life sciences, if we do not solve the problem of the reach and accessibility of research. We concur with your central premise that embedding trials into routine health care is an important way to address this.

A Complementary Framework: Cures in Community

Point-of-care platforms like the ones envisioned in the legislation's "Cures in Care Initiative" are necessary, but they are not sufficient. A platform is only as good as the number of patients who can reach it, the data infrastructure that powers it, and the cross-agency coordination that prioritizes and sustains it at a national level. We urge you to pair your infrastructure-building approach with a complementary set of provisions addressing the conditions that determine whether point-of-care trials actually reach the patients and communities they are intended to serve. Think of this as a complementary framework, "Cures in Community." It rests on four core elements:

1. Modernizing trial designs and processes so patients can actually enroll
2. Building the data infrastructure underpinning the platforms
3. Establishing a coordinating structure with real authority
4. Reducing administrative burdens that determine who can participate

1. Modernizing trial designs and processes so patients can actually enroll

The legislative summary is largely silent on the demand side of trial participation—the designs and criteria that exclude patients, the consent processes that confuse them, and the costs and other barriers that make participation infeasible even when patients are eligible and willing. Absent these types of reforms, point-of-care platforms risk becoming infrastructure that exists in communities but remains inaccessible or undesirable to the patients within them.

Legislation could create mandates for change by:

- Requiring researchers to use real-world data to demonstrate the feasibility of trial designs and justify inclusion-exclusion criteria;
- Directing IRBs to exercise their full authority to promote inclusivity and access in trial design, not just to mitigate risk, and to champion patient-centered consent;
- Requesting that researchers meaningfully engage patients and communities in trial design to ensure research questions, protocols, and participation requirements reflect their priorities and realities;
- Reframing eConsent as the expected default rather than merely an option;
- Clarifying that fair market compensation for participant time and expenses does not constitute undue inducement;

- Resolving the current ambiguity around routine care coverage for Medicare and Medicaid beneficiaries enrolled in trials;
- Excluding payments to clinical trial participants from gross income and expanding the exclusions for means-tested programs;
- Requiring studies to produce plain-language summaries and share them with participants;
- Addressing uncertainty about what individualized information from trials can legally be shared with participants; and
- Requiring researchers to plan for the return of results to participants.

2. Building the data infrastructure underpinning the platforms

Section 3 of the legislative summary directs agencies to align clinical research data requirements with "emerging CMS/ONC data and interoperability standards" but does not detail specific barriers that currently prevent this alignment. The Trusted Exchange Framework and Common Agreement (TEFCA) does not yet include research among its permitted purposes for health data exchange; patients can authorize their data to flow for treatment, payment, and public health, but not for research. We recommend the bill direct ONC to pursue adding research as a TEFCA Exchange Purpose, creating a "research-capable" EHR certification option, and ensuring that FHIR and USCDI+ data standards reflect research use cases rather than clinical and billing purposes alone.

We also recommend expanding access to and usability of CMS's and FDA's high-value datasets, building on initiatives like CMS's Virtual Research Data Center and FDA's openFDA APIs to enable researchers to securely analyze data in place.

3. Establishing a coordinating structure with real authority

Section 2 of the legislative summary assigns the Center for Clinical Trial Innovation (C3TI) within FDA's Center for Drug Evaluation and Research (CDER) as the centralized coordinating entity for the initiative. While we are strong proponents of C3TI and its efforts thus far, we do not believe a center housed within FDA's drug review division has the standing or the resources to coordinate CMS payment policy, ONC data standards, and NIH/ARPA-H platform investment, each of which is necessary for success.

Our recommendation is for a coordinating function that sits at the HHS secretary's level, designated explicitly to align FDA, CMS, ONC, NIH, and ARPA-H activities. A national coordinator for clinical trials and research within HHS would serve as a central hub to coordinate efforts across federal agencies to improve the efficiency and effectiveness of clinical trials. Its work should be driven by a national agenda and action plan for clinical trials Phase I-IV (not only Phase I), informed by a public-private partnership that brings together government, industry, academia, health systems, and patient groups. The agenda should set clear priorities for modernizing trial infrastructure and should address long-standing barriers that hinder patient participation and delay trial initiation.

The coordinator's responsibilities could include identifying evidence gaps in areas of high unmet need, developing national research challenges to address those gaps, and providing technical support and resources to new trial sites in community-based settings. We also recommend that it initiate an effort to build and maintain a national clinical trial and research network inventory, akin to what we were able to create during the pandemic, in order to have a comprehensive understanding of domestic research capacity.

Also in need of coordination across federal agencies is a unified approach to encouraging greater use and acceptability of pragmatic trial designs. Pragmatic trials are, by definition, embedded in health-care systems and test interventions in real-world settings, complementing traditional explanatory trials. Federal support for pragmatic trials is spread across FDA, NIH, and CMS without a coordinating framework that aligns their approaches, creates consistent incentives, or provides a clear pathway for sponsors seeking to conduct pragmatic studies. HHS should designate a cross-agency pragmatic trials working group charged

with developing a unified policy framework, calling out explicit regulatory pathways for pragmatic designs, and perhaps identifying priority areas for pragmatic research.

We were glad to see you look to Australia's clinical trial ecosystem in Section 6, proposing oversight of lower-risk Phase 1 trials modeled on Australia's CTN scheme. Australia's framework illustrates how clearly defined roles among regulators, ethics committees, sponsors, and research institutions can reduce duplicative review and accelerate trial start-up times while maintaining protections for trial participants. HHS should explore opportunities to apply elements of Australia's scheme in the US.

4. Reducing administrative burdens that determine who can participate

A final set of recommendations is directly relevant to whether research reaches the community and rural sites we are aiming to activate, rather than concentrating, as trials do today, in a small number of well-resourced academic centers. These are the kind of fixes our ENRICH-CT members cited as sometimes the deciding factor in whether a community health system or rural provider can feasibly host a trial at all.

We recommend the bill:

- Direct FDA and OHRP to issue joint guidance harmonizing their overlapping oversight requirements, standardizing the definition of "minimal risk" studies, and exploring a single submission process that satisfies both FDA safety reporting and OHRP continuing review;
- Direct FDA and OHRP to endorse single-IRB reliance agreements for multisite trials, building on models like SMART IRB, already used by more than 1,400 institutions, to close the gap between NIH's existing single-IRB policy and its uneven adoption elsewhere;
- Direct NIH and FDA to develop standardized master contract templates, ending the lengthy, customized site-agreement negotiations that routinely stall multisite trial start-up;
- Direct FDA to clarify the listing requirement under Form FDA 1572, which is now applied overconservatively because sponsors are uncertain as to who is deemed by FDA to make a "direct and significant contribution" to trial data; and
- Direct CMS to issue a standardized Medicare Coverage Analysis template or process for multisite studies, so that sites are not each repeating the same billing determination independently and for every trial.

Next Steps

The Milken Institute stands ready to serve as a resource as this proposal moves forward, drawing on the ENRICH-CT coalition's 90 member organizations and the detailed, implementation-ready recommendations from both of our recent initiatives. We would welcome a conversation with you or your staff to discuss these recommendations further.

Thank you again for your leadership on this issue.

Sincerely,

Esther Krofah
Executive Vice President, Health
Milken Institute