July 14, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
US Department of Health and Human Services
Washington, DC 20201

The Honorable Martin Makary, MD
Commissioner
US Food and Drug Administration
Silver Spring, MD 20993

Re: Request for Information: Ensuring Lawful Regulation and Unleashing Innovation To Make America Healthy Again – Docket ID AHRQ-2025-0001

Dear Secretary Kennedy and Commissioner Makary,

The FasterCures team at the Milken Institute is honored to provide its expert response to the Request for Information regarding Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again, as part of the President's Deregulatory Initiatives under Executive Order 14192.

As a nonprofit, nonpartisan think tank, the Milken Institute believes in the power of capital markets to address urgent social and economic challenges, thereby improving lives. Its guiding belief is that societies thrive when they cultivate an educated, healthy workforce, foster transparent and efficient capital markets, and sustain effective social institutions.

FasterCures,[1] of the Milken Institute,[2] is driven by a singular goal: to save lives by speeding scientific advancements to all patients. With an independent voice, FasterCures is working to build a system that is effective, efficient, and driven by a clear vision: working with our partners to build a patient-centric system where science is accelerated, unnecessary barriers are overcome, and lifesaving and life-enhancing treatments get to those who need them as rapidly and as safely as possible.

FasterCures is dedicated to promoting collaboration between the public and private sectors to enhance the infrastructure needed for more expansive and inclusive clinical research in the United States. To meet this need, in late 2023, we convened **Enabling Networks of Research Infrastructure for Community Health through Clinical Trials (ENRICH-CT**),[3] a multistakeholder initiative comprising more than 65 business, nonprofit, and government leaders. The coalition grew out of FasterCures' work on the role of the federal government[4] and the private sector[5] in building capacity for clinical research across the country, as well as democratizing access to trials and making them truly person-centric.[6] ENRICH-CT serves as a precompetitive forum to share best practices, support collective action on common challenges, and build an ecosystem of excellence that sustains the workforce, partnerships, resourcing, and technology needed

to effectively conduct research closer to communities. The ideas put forward in this letter reflect the work and input of that expert group.

ISSUES: HIGH VOLUME OF REGULATION AND FRACTURED OVERSIGHT

Clinical research is a central component of health care, which is one of the most highly regulated industries in the United States and globally.[7] Regulation of clinical trial conduct, data, and other policies aimed at protecting trial participants is vital. It also serves to establish parameters for integrating new thinking or technologies into trial conduct and review, facilitating the use of modern techniques that may benefit both trial sponsors and participants, and standardizing data requirements across various types of stakeholders.

While the intended benefit of regulations and policies governing clinical research is substantial, in practice, the unintended consequences of regulations aimed at changing clinical trial practices may cause undue burden and barriers to entry for established researchers, new entrants, and trial participants alike. Adding to the complications is that there are dozens of agencies and entities—including US federal and state governments, professional bodies, and international organizations—that define and govern various elements of the process, such as safety, efficacy, ethics, data oversight, accreditation, reporting, reimbursement, and more. Together, the high volume of regulation combined with fractured delegation of oversight responsibilities create burdens on conducting clinical research in a more efficient and effective manner that could be alleviated through careful streamlining of the policies and practices governing research.

Summary of Recommendations

I. **Align regulatory requirements and interpretations across oversight entities.**
II. **Use risk-based oversight to distinguish between low- and high-risk clinical research and inspections.**
III. **Streamline data collection policies and oversight, reconciling practice and regulation.**
IV. **Prioritize decentralized trials and remote monitoring.**
V. **Expand clinical research participation to local health-care providers and nontraditional stakeholders.**
VI. **Prioritize master contracts and legal agreements.**
VII. **Expand Centers for Medicare & Medicaid Services (CMS) incentives for research engagement.**

GOAL: ENABLING A STREAMLINED CLINICAL RESEARCH SYSTEM WITH LESS UNDUE BURDEN

Clinical research persistently struggles to engage participants. An unacceptably large number of trials are delayed or fail to launch because of slow or low enrollment, at enormous cost to sponsors and incalculable cost to patients when innovations are not pursued. The ecosystem has been aware of these challenges for decades, but individual and collective efforts to solve them have produced marginal improvements at best.

At this time of incredible scientific opportunity, we will only succeed if we can solve the challenge of the reach and accessibility of research. We have technology that we can better leverage to connect Americans in every corner of the country to cutting-edge research opportunities and innovative products to improve their health. It is also vital to streamline the conduct of trials, lowering their time and cost, to maintain US competitiveness in this critical industry.

The COVID-19 experience engendered fresh energy around systems-level change to improve the conduct of clinical research. The National Academies of Sciences, Engineering, and Medicine's Envisioning a Transformed Clinical Trials Enterprise for 2030[8] initiative and the Clinical Trials Transformation Initiative's Transforming Trials 2030[9] each called for trials to be more patient-centered and easily accessible, fully integrated into health processes, and dedicated to improving public health. There are ongoing efforts within agencies themselves to examine and address regulatory barriers that make bringing research closer to communities challenging; the US Food and Drug Administration (FDA), for instance, has finalized guidance on decentralized clinical trials,[10] is offering new guidance on informed consent,[11] and has created a Center for Clinical Trial Innovation[12] to spur pilots to demonstrate regulators' appetite for fresh approaches. A recent Call to Action[13] published by the American Society of Clinical Oncology recommends specific policy changes necessary to increase patient and local clinician access to trials.

Achieving the shared goal of more integrated, accessible clinical trials will require some fundamentally different approaches to engaging clinicians, sites, and patients that must be supported by regulatory frameworks and actions.

Through ENRICH-CT, FasterCures is crafting a vision and a suite of recommendations for how changes to policy and practice can streamline and reduce regulatory and administrative burdens to enable the conduct of clinical research in more places in the United States with more Americans. This RFI presents an opportunity to share that vision, along with some examples of the kind of actions the Department of Health and Human Services (HHS) can take that would alleviate the burden on research sponsors, sites, clinicians, and patients.

Those actions encompass a number of broad topics, including:

- Data collection, interoperability, and privacy;
- Clinical trial conduct and quality;
- Use of new technologies;
- Roles of nontraditional staff, including community health-care professionals or community-serving organizations;
- Risk mitigation;
- Reducing burdens of engagement and participation for sponsors, sites, and patients; and
- Broadening access via minimizing financial, geographic, or technology barriers for sites and participants.

The vision for clinical research that we are seeking to enable to increase access to research opportunities throughout the United States is one that is:

Embedded

- Regulatory frameworks support streamlined trials by reducing administrative burden while maintaining high ethical and quality standards.
- Clinical research opportunities are offered to people in the course of their clinical care.
- Trials are incorporated into routine clinical practice through technology and workflows.

Accessible

- Nontraditional institutions are able to play active roles in research conduct and participant engagement.
- Trials are streamlined to remove burden and expand participation for individuals and institutions.

Tech-enabled

- Technological infrastructure is equipped to integrate decentralized and remote approaches to trials whenever possible.
- Interoperability frameworks ensure both transparency and participant privacy, supporting collaboration and trust in research.

Patient-centric

- Trials are designed and conducted with a commitment to inclusivity, ensuring access and participation across broad patient populations.
- Potential participants can readily understand what is involved and what the benefits and risks may be, and are offered choices and support for their participation.
- Participants are protected and empowered to make their own decisions.

HHS can play a pivotal role in coordinating the agencies and offices under its umbrella—including the National Institutes of Health, FDA, CMS, Office for Human Research Protections (OHRP), Assistant Secretary for Technology Policy, Health Resources and Services Administration, and others—to enable streamlined, less burdensome clinical research that is accessible to all.

RECOMMENDATIONS

Currently, research oversight is dispersed across these various agencies and entities within HHS that have distinct missions and do not routinely coordinate or engage in targeted interagency efforts to harmonize interpretations or enforcement of oversight. Actions HHS can take to address this inefficiency include:

I. Harmonizing regulatory requirements and interpretations across different entities overseeing similar trial processes.

- Align FDA and OHRP regulations and interpretations on human subject protections and institutional review boards. Duplicative or conflicting processes related to waivers of informed consent, exempt research, and single Institutional Review Board (IRB) mandates result in confusion and inefficiency.
- Often, even if a central IRB is employed to review a study, many institutions run studies through their local IRBs as well, wasting time and effort for little added value.

II. Employing risk-based oversight of clinical investigations and inspections, differentiating between low- and high-risk research and activities.

Minimal-risk studies are currently not well-defined, leading many sponsors to treat all studies as if they pose the highest level of risk to patients. This can add unnecessary burdens of documentation, safety reporting, and monitoring to low-risk studies, such as those based on existing treatments with well-established safety profiles.

III. Streamlining data collection policies and oversight.

Current data collection policies and regulations reside in different agencies under HHS purview and often assume data collection practices from the time they were originally written without acknowledging the vast ways digitization has changed our ability to collect and share information.

FasterCures has identified multiple avenues through which the federal government can address this mismatch of practice and regulation:

- Re-examining privacy frameworks that are part of data use agreements, including Health Insurance Portability and Accountability Act safe harbor regulations.
- Aligning with the Trusted Exchange Framework and Common Agreement to allow for better health information exchange and to reduce the need for source data records to enhance the use of real-world data sources for the generation of fit-for-purpose real-world evidence.
- Focusing on critical data elements to reduce data overload in collection and analysis.
- Simplifying site-level documentation by allowing essential documents only and encouraging the use of electronic versions over paper versions.
- Solidifying streamlined patient- and provider-access to relevant health and research information and incentivizing health information exchange. CMS can continue building out the Data at the Point of Care[14] pilot program to better support research needs, in addition to aggregating claims information for providers to better care for Medicare beneficiaries and expanding data access within the Blue Button 2.015 standards-based application programming interface for research organizations, providers, and participants.

IV. Prioritizing decentralized trials and remote monitoring approaches.

Traditional trials often exclude patients for reasons related to geography, mobility, socioeconomic status, or caregiving responsibilities. HHS can enhance regulatory flexibility for telehealth to allow for the greater use of decentralized trials in routine care and across state lines.

V. Enabling participation in clinical research by more local healthcare professionals and other non-traditional parties.

Many oversight mechanisms still reflect a time when research was conducted by a single investigator at a single site, negating updates that are common in other industries, such as digital improvements and the ability of new entities and innovators to contribute. Outdated procedures add burden as well as confusion around responsibility and liability, leading to overly conservative interpretations that limit the willingness of research sponsors to adopt more flexible or common-sense practices and curtailing the participation of new types of entities.

Specifically, HHS could encourage further innovation by taking actions such as:

- Further clarifying the role of local healthcare professionals in FDA-registered trials to ensure the reduction of the burden on them to participate;
- Encouraging streamlined, fit-for-purpose Good Clinical Practice training for local clinicians and community-health workers to support trials;
- Clarifying liability frameworks for clinicians offering trials, possibly under federal tort claims or safe harbors for approved protocols;

- Lessening record keeping for drug disposal and drug accountability with products that have well-characterized safety profiles; and
- Reducing legal and documentation burdens for low-risk, community-based trial sites.

VI. Prioritizing master contracting and legal agreements.

Contracting and legal processes are routinely identified as the most burdensome parts of participating in research, and many studies are slow or fail to advance because of the debilitating burden of research start-up. These burdensome processes also limit the use of innovative research models such as master protocols or adaptive trials that benefit patients by reducing the need for placebo control arms and directly comparing new treatments to each other.

VII. Expanding incentives (e.g., quality improvement credits) at CMS for providers to refer patients to clinical trials.

CMS has, in the past, successfully incentivized innovative trial approaches and clinical research participation. For example, in April 2020, the agency offered credits in the Merit-based Incentive Payments System (MIPS) to physicians who participated in COVID-19 clinical trials.[16] Reinstating and expanding this initiative holds promise for increasing trial participation, especially as none of the 104 current 2025 MIPS improvement activities directly address clinical trials.[17] Allowing physicians who enroll patients in a broad range of clinical trial types to receive MIPS credits would bolster clinical research.

FasterCures and the members of the ENRICH-CT coalition look forward to continuing to engage and discuss with you these critical goals and the specific actions HHS can take to help the ecosystem achieve them on behalf of patients.

Sincerely,

Esther Krofah
Executive Vice President, Health
Milken Institute

---

[1] "FasterCures," Milken Institute, accessed June 30, 2025, https://milkeninstitute.org/health/fastercures.
[2] "Home page," Milken Institute, accessed June 30, 2025, https://milkeninstitute.org.
[3] "Enabling Networks of Research Infrastructure for Community Health Through Clinical Trials (ENRICH-CT)," Milken Institute, accessed June 30, 2025, https://milkeninstitute.org/health/fastercures/improving-rd-environment/community-based-research-infrastructure/enabling-networks-research-infrastructure-community-health-through-clinical-trials-enrich-ct.
[4] Kristin Schneeman and Alisha Sud, *Building Community-Based Infrastructure for Inclusive Research: Lessons from the Pandemic for Federal Action* (Milken Institute, May 23, 2022), https://milkeninstitute.org/content-hub/research-and-reports/reports/building-community-based-infrastructure-inclusive-research-lessons-pandemic-federal-action.

[5] Kristin Schneeman and Amanda Wagner Gee, *Building Community-Based Infrastructure for Inclusive Research: Engaging the Private Sector* (Milken Institute, March 16, 2023), https://milkeninstitute.org/content-hub/research-and-reports/reports/community-based-infrastructure-inclusive-research-engaging-private-sector.
[6] Esther Krofah, Freda Lewis-Hall, and Annalisa Jenkins, *Community-Based Infrastructure for Inclusive Research: Democratizing Access to Research* (Milken Institute, November 13, 2024), https://milkeninstitute.org/content-hub/research-and-reports/reports/community-based-infrastructure-democratizing-access-research.
[7] Stu Spikerman, "What Are the Most Regulated Industries? A Guide to Compliance," Tri-Link FTZ, March 31, 2025, https://trilinkftz.com/global-trade-regulatory-compliance/what-are-the-most-regulated-industries-a-comprehensive-guide-for-businesses-in-2025/.
[8] Carolyn Shore, Amanda Wagner Gee, and Theresa Wizemann, "Envisioning a Transformed Clinical Trials Enterprise for 2030: Proceedings of a Workshop," *National Academies Press* (November 2021), https://pubmed.ncbi.nlm.nih.gov/34752026/.
[9] "Transforming Trials 2030," Clinical Trials Transformation Initiative, accessed June 30, 2025, https://ctti-clinicaltrials.org/about/transforming-trials-2030/.
[10] "Conducting Clinical Trials with Decentralized Elements," US Food and Drug Administration, accessed June 30, 2025, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements.
[11] "Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards," US Food and Drug Administration, accessed June 30, 2025, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/key-information-and-facilitating-understanding-informed-consent-guidance-sponsors-investigators-and.
[12] "CDER Center for Clinical Trial Innovation (C3TI)," US Food and Drug Administration, accessed June 30, 2025, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-center-clinical-trial-innovation-c3ti.
[13] R. Donald Harvey et al., "A Call to Action to Advance Patient-Focused and Decentralized Clinical Trials," *Cancer* 130, no. 8 (January 2024): 1193-1203, https://doi.org/10.1002/cncr.35145.
[14] "Data at the Point of Care," US Centers for Medicare & Medicaid Services, accessed June 30, 2025, https://dpc.cms.gov/.
[15] "CMS Blue Button 2.0," US Centers for Medicare & Medicaid Services, accessed June 30, 2025, https://bluebutton.cms.gov/.
[16] "Trump Administration Champions Reporting of COVID-19 Clinical Trial Data Through Quality Payment Program, Announces New Clinical Trials Improvement Activity," US Centers for Medicare & Medicaid Services, April 20, 2020, https://www.cms.gov/newsroom/press-releases/trump-administration-champions-reporting-covid-19-clinical-trial-data-through-quality-payment.
[17] "2025 Improvement Activities: Traditional MIPS," US Centers for Medicare & Medicaid Services, accessed June 30, 2025, https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2025.