



## **Milken Institute Statement on HHS-Wide Effort to Strengthen American Leadership in Clinical Trials**

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Thank you, Secretary Kennedy, for prioritizing this set of issues. I applaud the actions taken today to strengthen the United States clinical trials ecosystem and sustain US leadership in biomedical innovation. The Milken Institute has been working for over two decades on the question of how to accelerate biomedical progress for patients. We share the conviction of all those in the room today that the United States' biomedical enterprise is one of the nation's greatest assets, a strategic national treasure that has improved and extended lives, fueled economic growth, and strengthened national security. Other countries have recognized the opportunity, and competition to dominate the sector is increasing from around the world.

While the United States remains the world's leading engine of biomedical research, fragmented and outdated infrastructure, complicated administrative processes, increased cost and complexity of clinical development, and uncertain investment risk are slowing the translation of scientific discovery into new treatments and cures. Clinical trials, in particular, remain one of the most significant bottlenecks between scientific discovery and patient impact.

**This is a fixable infrastructure problem, not a scientific one, and it is one that can be addressed through focused leadership and sustained action by both the public and private sectors.**

Over the last several years, the Milken Institute has built and led a multi-stakeholder coalition called [ENRICH-CT](#) (Enabling Networks of Research Infrastructure for Community Health through Clinical Trials). This coalition comprises 90 organizations spanning industry, health systems, technology companies, community-based organizations, government agencies, and more. This coalition is working together to solve an existential challenge—that over 80 percent of trials are delayed or fail to launch at all due to insufficient enrollment, and the vast majority of Americans do not have access to clinical trials. Data show that even for cancer patients, only about 7 percent participate in clinical trials. This summer, the ENRICH-CT coalition will publish an extensive set of recommendations to advance a more accessible clinical trial ecosystem.

Last year, the Milken Institute convened and consulted nearly 100 of today's foremost leaders across the biomedical research ecosystem to chart the next era of biomedical innovation. The initiative's first phase resulted in a report outlining six broad recommendations to strengthen [The Future of Biomedical Research and Innovation](#) in the US.

The insights from our ENRICH-CT coalition and our Future of Biomedical Research initiative have reinforced that maintaining US leadership in life sciences will require strong leadership and coordinated effort across sectors, coupled with sustained long-term investment in the clinical trials infrastructure that underpins biomedical research and innovation in this country.

We applaud HHS' leadership in addressing the barriers that have made it increasingly difficult to conduct early-stage clinical development in the US. While strengthening early-stage development is important, it is only one part of a larger continuum. **We call for three bold actions to move the country forward.**

1. **Every American should have the opportunity to participate in clinical research.** The US should invest in a national clinical trials infrastructure—we need more sustained clinical trial sites in more places and closer to communities. Clinical trials should be viewed as the strategic infrastructure it is—not unlike energy or telecommunications—and just as essential to the nation's health, economy,

and security. Long-term progress will depend on addressing the underlying infrastructure needs that make it easier to establish new sites that support more than one study at a time, leverage decentralized tools, reduce the burden at the front lines for investigators, and leverage technology to find, recruit, and maintain patient enrollment in clinical trial sites across the country. We call for HHS to establish a National Agenda for Clinical Trials as part of a National Life Sciences Strategy informed by a public-private partnership that brings together government, industry, academia, health systems, technology developers, and patient groups.

2. **HHS should designate a coordinator to advance near-term action to align federal activities.** HHS should establish an Office of the National Coordinator for Clinical Trials and Research to sustain long-term commitment to the implementation of crucial policy actions across numerous public- and private-sector stakeholders. Such action should include supporting a robust health data infrastructure that enables research and evidence generation. We recommend a number of steps ONC can take, for example, to make EHRs work better for research, including creating a “research-capable” certification option. We recommend that TEFCA add research as an Exchange Purpose, and ensure research needs are being addressed in FHIR and USCDI+ data standards.
3. **We must make it easier for patients and clinicians to participate in clinical trials.** We recommend HHS take actions to broaden eligibility criteria, reduce the cost of participating in trials to patients, and align policies across federal agencies to incentivize more pragmatic trial designs. Clear alignment and coordination are needed between FDA and the HHS Office of Human Research and Protections, where there are overlapping rules and duplication. CMS should take action to clarify reimbursement policies that limit uncertainty around permissible reimbursement and routine care coverage. Clear policies from CMS would also support broader adoption and acceptability in private insurance markets.

These are a limited but critical set of actions to speed up progress. Elevating this topic as a national priority from HHS is paramount. The Milken Institute stands ready to be a resource, bringing together the perspectives of the organizations in our ENRICH-CT coalition and Future of Biomedical Research initiative and the detailed, implementation-ready recommendations we've developed, to help build the durable, scalable infrastructure that keeps American biomedical innovation at the forefront for the next century.