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*"Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development"*

SUMMARY

## The Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is the independent nonprofit Congress created in 2007 to advance regulatory science and support the FDA. We are a convener; we do not lobby nor engage in regulatory activity.

## The Central Message

Over the past year, the Foundation independently convened stakeholders to discuss three challenges: early-stage drug development, oncology multi-regional clinical trials, and rare disease treatment development. Compared against HHS's *Operation TrialBlazer* roadmap, all three reports and the roadmap converge on helpful FDA reforms. Nonetheless, there is more to be done**.**

## Key Finding: Strong, Independent Convergence

The recommendations of stakeholders aligned closely with Operation TrialBlazer across five recurring themes:

- Clarity in communication: phase-appropriate requirements, clearer FDA terminology (e.g., replacing "clinical hold"), and consistency across review divisions.
- Reducing duplication: single-IRB reliance, reusable playbooks, computable protocols, less "over-answering" by industry.
- Modern, efficient trial designs: master protocols, adaptive/platform trials, network (hub-and-spoke) models, especially in oncology and rare disease.
- Better use of existing data: real-world data, registries, natural history, and a proposed AI-enabled rare-disease knowledge system.
- An accessible FDA and early engagement: new consultation channels and plain-language resources to prevent costly rework.

## Gaps Requiring Congressional Action

- National Phase 1 clinical trial capacity: No clear picture of where first-in-human trial capacity exists in the United States or how it's eroding; recommends federal funding for a network of Phase 1 "centers of excellence."
- Uneven trial-site distribution and a declining number of trial sites nationally, limiting patient access.
- Patient-centric, cross-trial screening/referral platforms (vs. today's trial-by-trial screening).
- Durable guidance: risk-based nonclinical/manufacturing standards need finalized (not provisional) FDA guidance.
- Interoperable data infrastructure (EHR-trial database integration) paired with strong cybersecurity.
- Streamlined multi-site contracting and budget negotiation processes, which currently delay trial start-up.

## Competitiveness vs. Patient Focus

Operation TrialBlazer is animated by concerns of global competitiveness (e.g., keeping trials onshore), while the Foundation's convenings were driven by patient access and outcomes. These should be seen as "two roads to the same destination," not competing priorities.

## Bottom Line

FDA and HHS can streamline rules and processes. The Subcommittee can help advance US biomedical innovation directly, including through Phase 1 capacity-building and remove barriers to trial participation.