A Roadmap for Increasing Efficiency in the Development of New Medicines

The Reagan-Udall Foundation for the FDA, in collaboration with the Biotechnology Innovation Organization (BIO), just released a new report detailing how the United States can modernize the clinical trial process and make America the best place to develop new medicines.

Key Recommendations

Modernize Investigational New Drug Requirements and Reviews to allow companies to start testing promising therapies sooner.

Enhance Phase 1 Clinical Trials by supporting more flexible trial designs and a greater inclusion of patient perspectives and AI-enabled tools.

Improve FDA-Sponsor Coordination by offering clearer, more consistent, and more frequent communication with trial sponsors.

Build a Dedicated Phase 1 Trial Infrastructure: Funding a network of Phase 1 trial sites would enable more efficient early-phase trial initiation and execution.

Mitigate Litigation Risk for Phase 1 Trial Sites: Lowering legal exposure for trial sponsors would lead to more research without compromising patients' safety.

To remain globally competitive, the United States must make it easier, faster, and cheaper to conduct early-stage research in America. These reforms will help preserve U.S. leadership in biotech and ensure American patients have access to lifesaving medicines.

Bio Biotechnology Innovation Organization