



FDA Explores Expediting Clinical Trials: Announces Ambitious New Drug Pilot Program

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On June 24, 2026, the Food and Drug Administration (FDA) published a notice of availability in the *Federal Register* requesting information and public comment on an Expedited Investigational New Drug (IND) pilot program. The proposed pilot program is part of the Trump administration's focus on taking steps to strengthen America's leadership in clinical research, accelerate the development of lifesaving treatments and ensure that patients have access to the most innovative therapies in the world.

In announcing the proposed pilot, FDA acknowledges the public health importance of access to novel therapies and the agency's commitment to streamlining requirements and innovating processes to advance its global regulatory leadership and facilitate early-stage research in the U.S. The notice also points out that in 2021, China surpassed the U.S. in global share of Phase 1 clinical trials, and identifies the implications of accelerating first in human (FIH) milestones in drug development, including for advancing innovation on behalf of patients. Ultimately, the pilot aims to test whether the proposed processes can accelerate Phase 1 FIH study initiation, an increasingly prominent area of policy focus for both the administration and lawmakers on Capitol Hill.

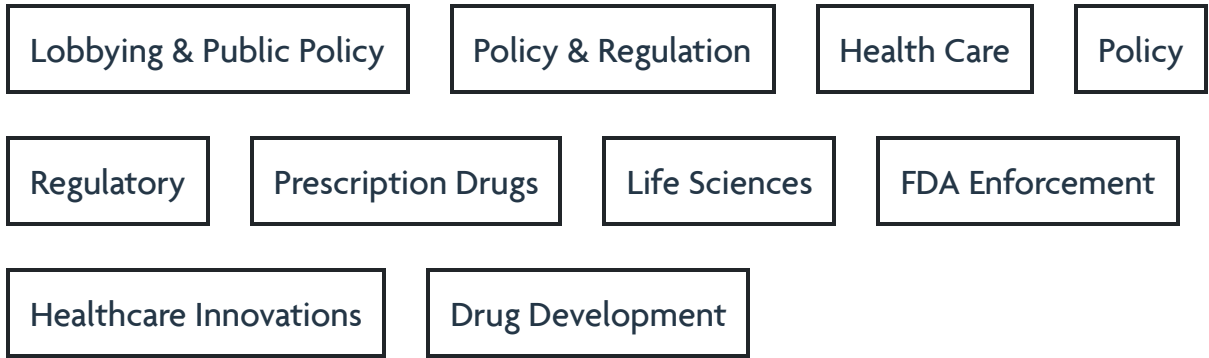
Through the proposed pilot, FDA seeks to leverage partnership with American research institutions in early clinical development for drugs by identifying a network of qualified research institutions (QRIs), such as academic medical centers, health care networks, contract research organizations (CROs), regulatory advisors and/or other research organizations, to potentially partner with sponsors to develop and review protocols for FIH clinical trials in the

U.S. intended for IND submission to FDA. The notice lays out the proposed role of QRIs, including responsibilities and criteria for qualification; however, FDA intends to review and refine QRI performance objectives and key deliverables, which could inform the agency establishing a process by which FDA certifies QRIs, in addition to monitoring and evaluating QRI performance against defined metrics. Notably, FDA plans to implement a new technology platform to perform a rolling IND submission by submitting individual IND components and receiving FDA feedback in real time, and through which, FDA will maintain oversight of recommendations regarding the program as the pilot does not alter FDA's regulatory authority and oversight with respect to INDs.

The notice establishes a public docket and seeks input from sponsors, CROs, academic institutions, health networks/systems, institutional review boards, patient advocacy organizations, investors and other interested parties. FDA has requested comments be submitted by July 22, 2026.

In seeking input on the proposed pilot program, FDA lays out a series of extensive questions related to the pilot program's design and implementation, risks, oversight, evaluation and additional considerations, including considerations and/or concerns not otherwise addressed in the questions posed in the notice. The comment period length implies FDA is looking to move quickly to receive input to inform additional information that may follow regarding how parties interested in serving as a QRI may request participation in the pilot. Interest in modernizing clinical trials has been a consistent area of bipartisan focus by Congress over the years, and these issues are likely to continue to be top of mind as Congress prepares to consider reauthorization of the Prescription Drug User Fee Act in the coming months. Congress may also consider how the proposed pilot fits within the legislative proposals highlighted in the agency's [Fiscal Year 2027 budget submission](#), which included a high-level proposal to create an expedited, risk-based alternative to the current IND pathway for certain Phase 1 trials.

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