

FDA's New Expedited IND Program

The Problem

The U.S. is losing its competitive advantage as the global leader in biomedical innovation and early phase clinical research to China, Australia, and increasingly, Europe. One roadblock, particularly for early-stage biotech, is the time from drug candidate identification to first-in-human (FIH) studies, which can take many months longer in the U.S. than elsewhere in the world. Sponsors that reach first-in-human milestones efficiently are better positioned to secure additional financial investments and well established to conduct later phase clinical research to enable approval of a safe and effective product for patients.

The Proposed Solution

To address this challenge, in September, FDA announced a new [Expedited IND Pilot Program](#), a component of HHS's [Operation TrialBlazer](#). The pilot program will evaluate whether partnering sponsors with third-party organizations, which FDA calls Qualified Research Institutions (QRIs), and incorporating a new rolling IND review process can improve the efficiency of early clinical development while maintaining FDA's rigorous standards for participant safety and scientific oversight. FDA has said lessons from the pilot may inform future efforts to certify or accredit QRIs, with the goal of building a sustainable, high-quality network of institutions to support drug development and accelerate the time to first-in-human trials.

Topline Summary of the Expedited IND Pilot Program

Under the pilot, QRIs, which are third parties that partner with a sponsor to develop an IND, are intended to provide expert recommendations to a sponsor on pharmacology; toxicology; clinical; and chemistry, manufacturing, and controls (CMC) components of FIH IND submissions. QRIs are intended to function as external scientific experts for the sponsor, providing risk-proportionate judgement similar to advice the sponsor might receive from FDA.

As a result, for an IND submitted by a sponsor/QRI collaboration, FDA will review IND components on a rolling basis before the full IND arrives, with the aim of resolving problems early, reducing the risk of a clinical hold, and ultimately reducing the time to FIH trial initiation.

FDA retains full regulatory authority under the pilot program and the sponsor is ultimately responsible for the IND, but by partnering sponsors with expert QRIs and enabling rolling review, the pilot is intended to reduce the time to FIH study start up.

Who Should Apply?

The program is targeted at sponsors developing novel products regulated by CDER, CBER, or the Oncology Center of Excellence (OCE). FDA will prioritize applicants developing new molecular entities that do not have prior clinical experience. Generic drugs, or new formulations, dosage forms, or combinations of existing active ingredients are not the primary focus of the pilot.

Sponsors must conduct the FIH trial in the US, under a commercial IND, and must have sufficient preliminary nonclinical data at the time the application to the pilot is submitted to allow FDA to reasonably evaluate the application and the QRI to provide meaningful input on the IND package.

A sponsor may submit an application for a single IND and must identify a partner QRI in the application.

What is a QRI?

A QRI is a third-party entity organized and incorporated in the US, with the requisite expertise to provide advisory support to the sponsor across nonclinical, CMC, and clinical disciplines of the identified IND. FDA will prioritize QRIs who also commit to supporting the acceleration of FIH clinical trial initiation in the United States through owned infrastructure or partnership arrangements.

According to FDA, QRIs could include academic medical centers (AMCs), health networks, contract research organizations (CROs), regulatory advisors, or other research organizations. Prospective QRIs that lack some required expertise in-house may contract with outside experts to fill those gaps. The QRI must have written conflict of interest procedures and manage its own conflict identification processes.

How to Apply?

Sponsors must partner with a QRI and submit the application according to the [instructions](#) on the application tab of FDA's Expedited IND Pilot website. FDA will evaluate the submissions against the criteria listed in the table below, and will select 8-10 sponsor-QRI pairs to participate in this first round of the pilot.

Sponsor	QRI
IND complexity and pilot fit	Non-clinical leadership / expertise
IND development stage	CMC leadership / expertise
Public health impact, unmet medical need	Clinical leadership / expertise
Sponsor profile	Clinical pharmacology
Portfolio considerations	Regulatory affairs leadership / expertise
	Program specific expertise
	Clinical phase 1 trial support

Timeline

- SEPTEMBER 15, 2026: Final pilot design announced, applications open
- **OCTOBER 30, 2026: APPLICATION DEADLINE**
- DECEMBER 18, 2026: FDA selects applicants

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