

Nguyen in Life Science Leader: FDA's Expedited IND Pilot Program

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Haynes Boone Associate [Luke Nguyen](#) authored an article for *Life Science Leader* on the FDA's Expedited Investigational New Drug (IND) Pilot Program, which aims to streamline early-stage drug development and accelerate the start of Phase 1 clinical trials in the U.S. The article explores how rolling submissions and early collaboration with qualified research institutions could help reduce regulatory delays and bring more clinical trials back to the U.S.

Read an excerpt below.

On average, the length of time between a sponsor's pre-IND meeting and final IND submission is more than a year. Accounting for the full spectrum of IRB and contractual requirements, this timeframe frequently balloons to two full years from the pre-IND meeting to the initiation of the Phase 1 trial.¹ This timeframe well exceeds the processes in other countries, such as China, which requires IND applicants to initiate the trial within 12 weeks of the applicable IND submission.² Other countries' reduced timeframes have led more and more sponsors to initiate Phase 1 trials abroad.

This shift could have consequences for patients in the United States. For example, in a recent webinar, FDA noted that such a shift could lead to less representative trial data; delays in patient access; and a reduction in the ability to respond to future emergencies (e.g., pandemics).

To reduce delays in early-stage drug development and entice early-stage trials to return to the United States, the Department of Health and Human Services (HHS) launched "Operation TrialBlazer." A key part of Operation TrialBlazer is FDA's Expedited IND Pilot Program (Pilot Program), which will test a new method of IND review in a selected cohort of sponsors. While far from a guaranteed future pathway, the Pilot Program is a significant step in modernizing FDA's IND pathway.

The (Potential) New Approach

The Pilot Program seeks to pair sponsors with Qualified Research Institutions (QRIs) early in the preclinical phase to streamline and improve IND submissions. Sponsors will be able to meet with QRIs on an ongoing basis, increasing the opportunity for real-time feedback and collaboration to expedite preparation of the full IND package. This should also limit the need for extensive, often time-consuming modifications to the pre-IND program that can follow a pre-IND meeting or FDA's review of the full IND package. In addition to the introduction of QRIs as resources in the pre-IND phase, FDA believes that the Pilot Program will improve efficiency by using a rolling IND submission process. In particular, the rolling IND submission process will allow the sponsor to submit components of the IND to FDA with questions and requests for feedback, and request meetings with FDA following development of individual components. As such, sponsors can receive feedback on the nonclinical; clinical; and chemistry, manufacturing, and controls (CMC) components and make any necessary updates before submitting the final IND package for review.

This is a major shift from the current IND process, in which sponsors have only one pre-IND meeting opportunity with FDA, which typically occurs once the IND package is nearly complete, and do not have QRIs to lean on during the pre-IND stage. The increased feedback from QRIs and FDA throughout the preclinical stage should allow FDA to expedite the review of the full IND package and, hopefully, reduce the 30-day window between submission and issuance of a “safe to proceed” notification or clinical hold letter.³

Separately, sponsors will be expected to receive IRB review prior to IND clearance. According to FDA, the goal is for the IRB review to occur concurrently with FDA’s review of the final IND package. For instance, once there is a draft clinical protocol, the draft protocol will be submitted to the IRB, rather than waiting for FDA to conclude its review. Currently, most IRB reviews occur after IND clearance, which can result in additional delays before initiation of the proposed clinical trial.

Read the full *Life Science Leader* article [here](#).