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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-4699]

Expedited Investigational New Drug Pilot Program; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information; establishment of a public docket.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is opening a public docket to solicit input and comments on a proposal to establish a pilot program, the Expedited Investigational New Drug (IND) pilot program, to shorten the time it takes from drug identification to first-in-human (FIH) study, while protecting clinical trial participants. FDA is requesting information on the potential pilot program which would establish a network of qualified research institutions, such as academic medical centers (AMCs), healthcare networks (HNs), contract research organizations (CROs), regulatory advisors, and/or other research or third-party review organizations (collectively called Qualified Research Institutions, or "QRIs"), who would partner with sponsors to develop and review protocols for FIH clinical trials intended for a IND submission to FDA. Information provided through this public docket will help the Agency refine our approach and consider other opportunities to accelerate time to FIH clinical trials.

DATES: Either electronic or written comments, data, or information must be received by July 22, 2026.

ADDRESSES: You may submit comments, data, and information as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 22, 2026. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for

information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include Docket No. FDA-2026-N-4699 for "Expedited Investigational New Drug Pilot Program; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the

docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Benjamin Cook, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 2, Rm. 2114, Silver Spring, MD 20993-0002, 240-338-4685, benjamin.cook@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to accelerating development of therapies and cures for the American people. In 2025, 70 percent of novel drugs were approved in the U.S. before any other country, meaning American patients and health care providers had access first.[1] However, other countries are focusing on increasing early-stage biomedical research and rapidly advancing in technical ability. For example, in 2021 China surpassed the U.S. in global share of phase 1 clinical trials, and from 2020 to 2025, 11 of the largest pharmaceutical companies spent over $150 billion to access early drug assets developed in China.[2] Given the public health importance of access to novel therapies, FDA is committed to streamlining requirements and innovating processes to advance our global regulatory leadership and facilitate early-stage research to continue in the U.S.

Biopharmaceutical companies able to accelerate FIH milestones have a material advantage in creating a successful novel therapy that reaches patients, which may be because the FIH milestone assists in securing partnerships, investment, and ultimately approved therapies. Early human clinical data represents the first value inflection point, and unlocks the additional investment required for late-stage development critical to the

[1] https://www.fda.gov/media/190705/download?attachment
[2] https://www.nature.com/articles/d43747-025-00065-7

marketing of safe and effective drugs. It is imperative for the U.S. to foster early clinical development that ultimately provides patients with access to novel therapies, and partnering with the innovation ecosystems and streamlining regulatory requirements may help achieve that goal.

FDA reviewers manage substantial portfolios of INDs, New Drug Applications (NDAs) / Biologics License Application (BLAs), and postmarket responsibilities. FDA aims to provide a regulatory environment for sponsors to accelerate early clinical development while maintaining rigorous oversight and safety protections for clinical trial participants. This requires reimagining the IND process to address regulatory considerations that account for pressures facing U.S. innovators who seek to develop safe and effective drugs and longstanding resource constraints facing FDA reviewers. The proposed pilot program is being designed to test the feasibility of helping to address overall time to the first in human trials. Specifically, the pilot aims to test whether it is possible to improve the quality of IND submissions such that there are fewer instances where it is necessary to impose phase 1 clinical holds; reduce FDA review time through a rolling submission process; and test whether clinical trial initiation activities, such as Institutional Review Board (IRB) review and site contracting, can be conducted in parallel with IND development and review, thereby accelerating the time from when FDA permits a clinical investigation to begin to FIH study initiation.

The role of third parties during the initial pilot program will be restricted to providing advice and preliminary review, not engaging in regulatory decision-making. FDA will remain solely responsible for making decisions about whether a clinical investigation can begin or whether a clinical hold may be imposed. Participation in the pilot is voluntary. Sponsors may continue to submit INDs to FDA without participating in the pilot.

A. Proposed Expedited IND Pilot Program Structure:

FDA proposes leveraging America's world-class research institutions as

collaborative partners in early clinical development for drugs intended for commercial distribution. The proposed expedited IND pilot program will serve to identify a network of qualified research institutions, such as AMCs, HNs, CROs, regulatory advisors, and/or other research organizations (collectively called QRIs), who will partner with sponsors to develop and review protocols for FIH clinical trials in the U.S. intended for IND submission to FDA. These QRIs would specifically assess and make recommendations for the pharmacology and toxicology, clinical, and chemistry, manufacturing and controls (CMC) components of the Phase 1 FIH IND submission. QRIs are intended to serve as expert partners to sponsors in developing higher-quality submissions that will expedite the timeframe to FIH trials and QRI recommendations are, by nature, advisory. Sponsors will maintain ownership over the IND submission. Throughout the proposed pilot, FDA will maintain full oversight of IND submissions, retaining full authority to make regulatory determinations, including the ability to issue a clinical hold, disqualify investigators, and conduct inspections.

As part of the proposed pilot, FDA is exploring the use of a rolling submission platform that would allow FDA to review QRI recommendations regarding completed components of the IND submission on a rolling basis. Similar to the rolling review of an NDA or BLA under FDA's expedited review programs, this approach would facilitate FDA review of completed individual IND components prior to formal IND submission. Once the last component of the Phase 1 IND is submitted, the IND would be considered submitted such that the 30-day IND review clock starts. Since all the IND submission components would have been reviewed by FDA on a rolling basis, the sponsor may receive a safe to proceed notification before the 30-day IND review period ends. The rolling review could minimize the need for FDA to impose a clinical hold because it would provide an earlier opportunity for FDA to identify deficiencies, prior to the 30-day review period starting. Similarly, the rolling review could minimize the need for FDA to

issue a clinical hold or information request. The pilot aims to test whether these processes may accelerate Phase 1 FIH study initiation.

Additionally, FDA intends to work with sponsors and QRIs to review and refine QRI performance objectives and key deliverables as part of the pilot, with the goal of gathering information that could inform a potential process for establishing a process for QRI certification by FDA. FDA will monitor and evaluate QRI performance through clearly defined metrics. FDA will implement a new technology platform to perform a rolling IND submission by submitting individual IND components and receiving FDA feedback in real time. Using this platform, FDA will maintain oversight of recommendations regarding the program's clinical protocol, pharmacology and toxicology package, or CMC package, and ultimately provide FDA with the necessary information to expedite IND submission review. FDA would retain full regulatory authority including:

- Authority to disqualify an investigator from conducting clinical research;
- Authority to disqualify or impose other administrative restrictions on an IRB or its parent institution;
- Current Good Clinical Practice clinical trial inspection program;
- Requirements for safety reporting;
- Ability to issue a clinical hold.

The goal of this new pilot program is to accelerate the time from nonclinical research to FIH studies while maintaining full FDA oversight and regulatory authority. FDA seeks stakeholder input on the processes, operational requirements, structural factors, and other considerations that may impact pilot implementation. At the conclusion of the pilot, FDA intends to use learnings from the pilot to further provide regulatory oversight that facilitates early-stage, first in human research in the U.S., and potentially refine its IND review process broadly going forward. Following the pilot,

FDA expects that sponsors will pay fees directly to QRIs. FDA will not be involved in the setting or collection of any fees.

B. QRI Responsibilities:

FDA is considering the following responsibilities for QRIs participating in the proposed pilot. FDA is seeking input on the appropriate scope and structure of these responsibilities through questions outlined in Section II. For the purpose of the pilot, QRI responsibilities would include:

- Conducting conflict of interest screening and establishing a formal engagement agreement with the sponsor;
- Conducting regular meetings with the sponsor and appropriate subject matter experts to discuss IND development progress, and maintaining comprehensive documentation of discussions and recommendations;
- Providing expert consultation and written recommendations to sponsors on nonclinical, clinical, and CMC components of the IND submission on a rolling basis;
- Maintaining documentation of recommendations and sponsor interactions and sharing with FDA through the rolling submission platform;
- Supporting parallel activities such as IRB review and clinical trial site activation to facilitate timely trial initiation upon FDA IND review; and
- Participating in pilot evaluation activities, including providing metrics and lessons learned to FDA.

C. QRI Qualification Criteria:

The following reflects FDA's current thinking on eligibility criteria for consideration for participating in the proposed pilot program as a QRI. For the purposes of the proposed pilot, QRIs would be expected to demonstrate:

- Comprehensive expertise across nonclinical (pharmacology/toxicology), clinical,

and CMC disciplines relevant to first-in-human IND submissions;

- Clinical trial infrastructure supporting Phase 1 studies, including IRB and clinical trial site capabilities, either through direct ownership and operation or through established partnerships;
- Leadership and personnel with suitable drug development and first-in-human IND execution expertise across relevant disciplines, including pharmacology-toxicology, clinical, CMC, and regulatory affairs; and
- A track record of success in regulatory affairs, including supporting IND submissions across relevant therapeutic areas and product modalities

FDA will encourage pilot applicants to describe their capabilities based on the qualifications outlined above. Additional capabilities may be described if they advance applicants' ability to support IND development.

II. Considerations for Pilot Development

FDA seeks input on these topics from sponsors, contract research organizations, academic institutions, health networks/systems, institutional review boards, patient advocacy organizations, investors, and other interested parties. To help FDA review comments efficiently, please identify the question to which you are responding by its associated category and number. If you are responding to more than one question, please identify each question to which you are responding, and categorize each response by question. After reviewing input provided on these topics, FDA intends to provide additional information about how QRIs can request to participate in the pilot.

A. Pilot Program Design and Implementation

1. QRI Qualification and Capabilities:

i. What specific changes, if any, would you recommend regarding FDA's thinking on the capabilities, infrastructure, and/or leadership expertise research institutions must demonstrate to qualify for the pilot program?

ii. Are there additional required capabilities FDA should assess across clinical and translational science expertise, CMC capabilities, or therapy/domain area knowledge?

iii. Are any of the listed QRI qualification considerations unfeasible or unattainable by potential QRIs?

iv. Should different specializations exist based on QRI therapeutic area focus or therapeutic modality expertise?

v. To ensure faster FIH initiation, should QRIs be required to have a self-owned and operated IRB and/or clinical trial site? If not, would a partnership with an IRB and/or trial site network be sufficient?

vi. If the QRI serves in a dual capacity as both an IRB and regulatory advisor, are there additional considerations or reporting that would be helpful to prevent potential conflicts of interest and ensure QRIs are objective and reliable?

2. Pre-IND and IND Review Process:

i. What changes, if any, would you recommend regarding QRI responsibilities and expected tasks during the pilot? Are any tasks unfeasible or should be undertaken by the sponsor rather than the QRI?

ii. What should be the output of QRI advice and review? What information from this review should be submitted to FDA?

iii. How can the pilot ensure QRIs provide independent, objective review while partnering with sponsors?

iv. How should expedited INDs during the pilot differ in requirement from standard IND submission, if at all?

3. Drug Eligibility and Participation:

i. Should all drug products be considered in the pilot or are there specific types of drug products and/or specific disease or conditions that are better suited for the pilot (e.g., small molecules, large molecules, cellular & gene therapies, nucleic acid-based therapies, combination products, etc.)?

ii. How should drug products be prioritized for participation in the pilot and why?

4. Pilot Scope and Scale:

i. How many QRIs and therapeutic areas / modalities be included in the pilot to represent industry research and different public health needs?

ii. What duration or volume of participation is appropriate for the pilot phase before evaluation?

5. Implementation and Feasibility:

i. What resources would QRIs need to develop and maintain IND review and recommendation capabilities (staff, quality systems, technology infrastructure, estimated costs)?

ii. Are there existing models, research networks, pilot programs, or international examples that could inform implementation? Please describe relevant examples and lessons learned.

B. Risks, Oversight, and Evaluation

1. Risks and Safeguards:

i. Are there any risks worth noting associated with the proposed pilot program?

ii. Could the pilot inadvertently compromise clinical trial participants' safety, scientific rigor, or ethical standards, and if so, what suggestions does the commenter have for mitigating such an outcome?

iii. Could this pilot create inequitable access favoring well-resourced sponsors over smaller companies?

iv. Please include how identified risks can be mitigated.

2. Oversight and Accountability:

i. In the case of disagreement between FDA and QRIs/sponsors on recommendations, what processes, timeline, discussion forums, or mitigation should be used to quickly reach a resolution?

ii. What oversight and compliance mechanisms should apply if QRIs fail to meet performance standards? What performance thresholds or other events should trigger FDA intervention or removal of QRIs?

iii. How can the pilot ensure transparency while safeguarding the sponsor's confidential commercial, trade secrets, and other sensitive information?

3. Success Metrics and Evaluation:

i. What data should be collected throughout the pilot to enable evaluation? Who should collect this data (FDA, QRIs, sponsors, third party evaluators)?

ii. What metrics should define pilot success? Please address time, quality, safety, and specify any others.

iii. At what point is the pilot deemed successful (i.e., after the first successful IND submission, after the entire pilot cohort is finished with IND submission, etc.)?

iv. If successful, how should the pilot expand? How can innovation from the pilot be scaled to maximize impact for the FIH clinical trial ecosystem?

C. Additional Considerations

1. What additional/alternative approaches could achieve similar goals of accelerating Phase 1 FIH IND study initiation in the U.S.?

2. What are the advantages and disadvantages of the proposed pilot compared to these alternatives?

3. How should FDA take into account the information submitted, and should that be different depending on the risk of the product under investigation?

4. Are there important considerations or concerns not addressed in the questions above?

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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