FDA Operation TrialBlazer: The Expedited IND Pilot Program

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Executive Summary

On **June 22, 2026**, the U.S. Department of Health and Human Services (**HHS**) launched **Operation TrialBlazer**, a department-wide roadmap coordinating FDA, the National Institutes of Health, the Advanced Research Projects Agency for Health, and the HHS Office of Inspector General around keeping early clinical research based in the United States (hhs.gov). The most consequential action for early-stage sponsors is the proposed **Expedited Investigational New Drug (IND) Pilot Program**, opened for public comment via a Federal Register notice on **June 24, 2026** under Docket No. **FDA-2026-N-4699** (www.govinfo.gov). As of **August 2026**, this remains a **request for information (RFI)**, not an established program: FDA labeled it "Notice; request for information; establishment of a public docket" (www.govinfo.gov), and the original **July 22, 2026** deadline was extended; comments are due by **11:59 p.m. ET on August 24, 2026** (www.fda.gov). FDA also held an educational stakeholder webinar on **August 6, 2026**, and says it is seeking feedback before initiating the program (www.fda.gov).

The proposal would let sponsors voluntarily partner with a new class of third party, **Qualified Research Institutions (QRIs)**, potentially including academic medical centers, healthcare networks, contract research organizations, and regulatory advisors (www.govinfo.gov), to pre-review Phase 1 first-in-human protocols and support rolling IND submission. FDA is explicit that QRIs would be "restricted to providing advice and preliminary review, not engaging in regulatory decision-making" (www.govinfo.gov), that participation "is voluntary" (www.govinfo.gov), and that, following the pilot, FDA expects sponsors to pay fees directly to QRIs outside FDA's involvement; the RFI does not establish fees during the initial pilot (www.govinfo.gov). Critically, the underlying **30-day regulatory IND review clock** is unchanged; FDA states that it starts once the last Phase 1 IND component is submitted (www.govinfo.gov).

HHS frames the initiative around competitiveness with China, whose share of global Phase 1 trials "surpassed the United States' share" in 2021 (hhs.gov) (www.arnoldporter.com) and reached "39% of global trials" by 2024 (hhs.gov), against a U.S. average of **380 days** between a pre-IND meeting request and IND submission (hhs.gov). FDA says its updated Phase 1 CMC webpage, which clarifies phase-specific requirements, can save companies **6 to 12 months** of development time by focusing on phase-appropriate requirements (www.fda.gov). This action does not depend on the pilot's outcome. TrialBlazer also includes revised draft guidance on substantial evidence of effectiveness for later-stage approval standards, with comments due **September 22, 2026** (www.fda.gov), and a separate, statutorily distinct "expedited IND pathway" that FDA has asked Congress to create through its fiscal year 2027 budget request, which Ropes & Gray describes as "markedly different" from the RFI pilot (www.ropesgray.com).

This report distinguishes proposal from policy, explains the current IND and first-in-human pathway, compares the pilot to FDA's four established expedited programs (none of which target the pre-IND window), and covers eligibility considerations, open questions on equitable access and safety, and practical next steps sponsors should track. As

of publication, FDA has not finalized pilot design, named QRIs, or set a launch date. Sponsors can review the CMC resources and nonclinical draft guidance now as statements of FDA's current thinking, but they are nonbinding and do not change existing IND requirements.

Introduction and Background

On **June 22, 2026**, the U.S. Department of Health and Human Services (**HHS**) announced **Operation TrialBlazer**, a coordinated, department-wide roadmap intended to keep early-stage clinical research anchored in the United States (hhs.gov). The accompanying HHS roadmap document frames the effort as a response to competitive pressure, stating that the goal is to "eliminate the unnecessary delays, redundant requirements, and regulatory ambiguity" that the agency says currently slow domestic drug development (hhs.gov). HHS Secretary **Robert F. Kennedy Jr.** framed the initiative around reversing the outflow of trials from the U.S., stating "we have built a system that drives too much clinical research overseas" (www.hhs.gov).

As part of TrialBlazer, the **U.S. Food and Drug Administration** (**FDA**) is pursuing several parallel actions across the drug development lifecycle. The most consequential for early-stage sponsors is a **proposed** pilot: the **Expedited Investigational New Drug (IND) Pilot Program**, opened for public comment via a Federal Register notice on **June 24, 2026** under Docket No. **FDA-2026-N-4699** (www.govinfo.gov). The Expedited IND pilot remains an **RFI**, not a finalized program or FDA policy.

To understand what the pilot would change, sponsors first need a clear picture of how IND review works today, since the reforms are calibrated against that baseline. This report walks through the existing IND and first-in-human (**FIH**) pathway, the mechanics of the proposed pilot, the other TrialBlazer actions bearing on Phase 1 and later-stage development, likely sponsor eligibility and readiness considerations, and the open questions FDA itself has posed to the public. Analysis reflects the perspective of a life-sciences and AI consulting practice, not participation in or endorsement by FDA or any Qualified Research Institution under the proposed pilot.

Key Changes

How the Current IND and First-in-Human Process Works

Before a company can dose a human volunteer with an investigational drug, it must submit an **IND application** to FDA. FDA states that an IND "is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans" (www.fda.gov). Legally, it is not a marketing application at all, but "a request for an exemption from the Federal statute that prohibits an unapproved drug from being shipped in interstate commerce" (www.fda.gov), and the underlying regulations sit in **Title 21, Code of Federal Regulations, Part 312** (www.fda.gov).

Once FDA receives an IND, a 30-day regulatory review period begins. FDA states that "the review time for initial submission of an Investigational New Drug application is 30 days from the date FDA receives the IND" (www.fda.gov), and that studies "shall not be initiated until 30 days after the date of receipt of the IND by FDA" absent earlier notification (www.fda.gov). Arnold & Porter's summary of current practice is consistent: "a sponsor

must wait 30 days from the date that FDA receives an IND to begin a clinical study" (www.arnoldporter.com). An investigator "may not administer an investigational new drug to human subjects until the IND application goes into effect" (www.fda.gov).

A standard IND submission bundles three broad categories of evidence:

- **Preclinical (nonclinical) data**, including animal pharmacology and toxicology study results, to permit "an assessment as to whether the product is reasonably safe for initial testing in humans" (www.fda.gov), described elsewhere by FDA as "animal study data and toxicity" information (www.fda.gov).
- **Chemistry, Manufacturing, and Controls (CMC)** information describing how the drug is produced, tested, and packaged.
- **Clinical protocols and investigator information**, describing the proposed trial design and the qualifications of the physicians who will run it.

If FDA identifies a safety problem, it can issue a **clinical hold**, defined as "an order issued by FDA to the sponsor of an IND application to delay a proposed clinical investigation or to suspend an ongoing investigation" (www.fda.gov). Grounds for a hold on a Phase 1 study include cases where "human subjects are or would be exposed to an unreasonable and significant risk of illness or injury" (www.fda.gov); for later-phase studies, a hold can also apply if "the plan or protocol for the investigation is clearly deficient in design to meet its stated objectives" (www.fda.gov). A sponsor "may not proceed with a clinical trial on which a clinical hold has been imposed until the applicant has been notified" that it has been lifted (www.fda.gov), though FDA notes such holds are "rare," and the agency "often provides comments intended to improve the quality" of a trial rather than stopping it outright (www.fda.gov).

Phase 1 trials, the first stage of human testing that the pilot targets, typically enroll "20 to 100 healthy volunteers or people with the disease/condition" over several months to assess safety and dosage (www.fda.gov), and FDA reports that "approximately 70% of drugs move to the next phase" (www.fda.gov). **Phase 2** studies scale to "up to several hundred people with the disease/condition" over months to two years (www.fda.gov), while **Phase 3** trials expand to "300 to 3,000 volunteers who have the disease or condition" over one to four years (www.fda.gov). Before filing a marketing application, FDA generally expects "adequate data from two large, controlled clinical trials" (www.fda.gov), a standard the Substantial Evidence Guidance discussed below would revisit.

Why HHS and FDA Launched Operation TrialBlazer

The roadmap's core argument is competitive: the United States has historically dominated early clinical research, but the HHS document warns that "China has made biotechnology a strategic national priority" (hhs.gov) and cites a national security commission's warning that the country has "a critical window, measured in years, not decades, to act decisively" (hhs.gov). The roadmap states that "China's global share of Phase 1 trials surpassed the United States' share" in **2021** (hhs.gov) (www.arnoldporter.com), and that by **2024** China had "over 7,100 registered" trials, "representing 39% of global trials" (hhs.gov), a figure independently corroborated by outside legal analysis of the same roadmap (www.spencerfane.com).

Beyond trial counts, HHS points to capital flows: it states that "global companies spent over $137 billion on licensing China-based assets" in **2025** (hhs.gov), while the Federal Register notice itself states that "from 2020 to 2025, 11 of the largest pharmaceutical companies spent over $150 billion" acquiring early drug assets originating in China (www.govinfo.gov); a public comment filed with the docket separately cites pipeline data showing "46% of all new drug molecules entering first-in-human clinical trials in the first half of 2025" originated with Chinese companies

(schaeffer.usc.edu). These figures reflect different data sets and time windows but point in the same direction. HHS also emphasizes what is at stake domestically, noting that "over half of all new drugs launch first in the U.S." today (hhs.gov), and separately, the Federal Register notice states that "70 percent of novel drugs were approved in the U.S. before any other country" (www.govinfo.gov) as of the most recent year cited.

The roadmap states the "average" time "between a Pre-IND meeting request and IND submission" in the U.S. is **380 days**, "with a range of almost 700 days" (hhs.gov), a figure trade press also reports as sitting "at 380 days" (hitconsultant.net). HHS also states that "sponsors often must wait up to 60 days just to have a pre-IND meeting" with FDA in the first place (hhs.gov), and that post-IND, "IRB review and contract negotiation" "can add up to 13 months of additional delay before a single patient is enrolled" (hhs.gov). At **BIO 2026**, acting CBER (Center for Biologics Evaluation and Research) Director **Karim Mikhail** described the constraint sponsors face under the current single-meeting model, saying "you have this one chance, and one chance only, to be in front of the FDA" (www.biospace.com).

The Proposed Expedited IND Pilot Program and Qualified Research Institutions

The centerpiece of FDA's early-development actions is the proposed **Expedited IND Pilot Program**, which the Federal Register notice describes as intended to "shorten the time it takes from drug identification to first-in-human (FIH) study, while protecting clinical trial participants" (www.govinfo.gov). The mechanism is a new class of third-party entity FDA calls a **Qualified Research Institution (QRI)**, a category that could include "academic medical centers (AMCs), healthcare networks (HNs), contract research organizations (CROs), regulatory advisors" and other research or review organizations (www.govinfo.gov). Under the proposal, QRIs would "partner with sponsors to develop and review protocols for FIH clinical trials" before those protocols reach FDA (www.govinfo.gov).

Several design choices in the RFI matter for how sponsors should read this proposal:

- **Advisory, not regulatory, authority.** FDA is explicit that QRIs would be "restricted to providing advice and preliminary review, not engaging in regulatory decision-making" (www.govinfo.gov). Arnold & Porter's analysis of the same notice similarly concludes that "FDA is clear that it would retain full regulatory oversight of the IND submission" (www.arnoldporter.com), and Ropes & Gray describes QRIs as serving "in a purely advisory capacity during the pilot" (www.ropesgray.com).
- **QRI input is advisory; sponsors retain IND ownership.** FDA's notice states that "QRI recommendations are, by nature, advisory," and that sponsors "will maintain ownership over the IND submission" (www.govinfo.gov). FDA retains regulatory decision-making authority.
- **Voluntary participation.** FDA states plainly that "participation in the pilot is voluntary," and that sponsors "may continue to submit INDs to FDA without participating in the pilot" (www.govinfo.gov).
- **Potential post-pilot sponsor-paid fees outside FDA's control.** FDA expects that, following the pilot, sponsors will pay fees directly to QRIs and says it will not be involved in setting or collecting fees. The RFI does not establish fees during the initial pilot (www.govinfo.gov).

Arnold & Porter warns this fee structure and the limited initial pool of eligible institutions could create "a race for centers to become qualified QRIs and for sponsors and other parties to contract with those centers first" (www.arnoldporter.com), a dynamic worth watching for smaller or resource-constrained sponsors.

Rolling IND Submission and the 30-Day Review Clock

A second mechanical change under the proposal is a **rolling submission** concept. Rather than waiting to assemble a complete IND before filing, sponsors working through a QRI could have individual components (nonclinical, clinical, and CMC sections) reviewed as they are completed. The Federal Register notice frames this as testing 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" (www.govinfo.gov), and as testing whether higher-quality submissions produced with QRI input can "improve the quality of IND submissions such that there are fewer instances where it is necessary to impose phase 1 clinical holds" (www.govinfo.gov).

Importantly, the **30-day regulatory IND review clock** itself is not eliminated. The notice specifies that once the last IND component is submitted, "the 30-day IND review clock starts" as under current rules (www.govinfo.gov). Because components are reviewed incrementally, the notice indicates a sponsor "may receive a safe to proceed notification before the 30-day IND review period ends" (www.govinfo.gov), which is where the time savings would come from, not from shortening the underlying regulatory review period. FDA also states it retains its full existing enforcement toolkit throughout the pilot, including the "ability to issue a clinical hold" (www.govinfo.gov) at any point.

Ropes & Gray flags a practical limitation of this design: sponsors who already have deep in-house nonclinical, clinical, and CMC expertise, and who would not otherwise use a QRI, may see little advantage, since "there would be little benefit to biotech companies that choose not to work with QRIs" (www.ropesgray.com). Any future QRI engagement fees and time would need to be weighed against the diligence-quality benefit alone; FDA has not established pilot-period fees.

Phase-Appropriate CMC Resource and Nonclinical Testing Reforms

Alongside the pilot, FDA updated its Phase 1 IND CMC webpage for CDER-regulated drugs to clarify phase-specific CMC requirements for first-in-human Phase 1 INDs. FDA says the resource is intended to help companies generate and submit only the data needed at that stage; it says focusing on phase-appropriate requirements can save companies **6 to 12 months** of development time (www.fda.gov).

FDA is separately pursuing a "risk-based approach toward nonclinical safety studies to relieve certain sponsors from conducting unnecessary animal testing" (www.arnoldporter.com), an effort the roadmap justifies by noting that pharmacology and toxicology testing for "the development of a monoclonal antibody may use hundreds of animals" under current practice (hhs.gov), with a stated goal to "eliminate unnecessary animal toxicology studies that may add substantially to drug development timelines" (hhs.gov). This builds on FDA's December 2025 draft guidance, "Monoclonal Antibodies: Streamlined Nonclinical Safety Studies" (hhs.gov). The document is labeled "Not for implementation" and, as draft guidance, reflects FDA's current thinking rather than changing existing IND requirements.

FDA is also revisiting how many pre-IND touchpoints sponsors get. Acting CBER Director Mikhail's BIO 2026 comments, cited above, describe existing guidance as not designed "for Phase 1, first-in-human IND submission" (www.biospace.com), a critique echoed by a public comment noting FDA's "guidance document on INDs for Phase 1 studies was written in 1995" (schaeffer.usc.edu), thirty-plus years before TrialBlazer's launch.

Revised Substantial Evidence Guidance for Late-Stage Trials

TrialBlazer is not limited to Phase 1. FDA is also circulating a significantly revised draft of its **Substantial Evidence Guidance**, which governs the type and quantity of clinical data needed to demonstrate a drug's effectiveness for approval, most relevant to sponsors already in Phase 2 and Phase 3. HHS's own announcement materials describe a proposed approach under which "one high-quality late-stage clinical trial with confirmatory evidence will generally be sufficient" in appropriate cases (www.hhs.gov), rather than FDA's longstanding general expectation of data from two large, controlled trials. The revised Substantial Evidence document is draft, nonbinding guidance that reflects current thinking; it does not itself change approval requirements.

FDA states that the revised draft guidance discusses how sponsors can rely on one adequate and well-controlled clinical investigation with confirmatory evidence to satisfy the substantial-evidence standard, and that, when final, it will replace the 1998 guidance. FDA lists **September 22, 2026** as the deadline for comments (www.fda.gov). Because this guidance affects the evidentiary bar for approval rather than the FIH pathway, sponsors should treat it as a separate, though related, workstream from the Expedited IND pilot.

Related to Phase 1 specifically, FDA issued draft guidance titled **"Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials"** (www.fda.gov). FDA identifies it as draft, nonbinding guidance and lists Docket No. **FDA-2026-D-6539**.

A Separate Statutory Proposal: The FY2027 Budget's "Expedited IND Pathway"

Sponsors researching this topic will likely encounter a second, differently scoped idea that also uses the term "expedited IND," which creates real potential for confusion. Separately from the RFI pilot, Arnold & Porter reports that "FDA has asked Congress to create an expedited IND pathway in its fiscal year 2027 budget request" (www.arnoldporter.com). Cooley similarly notes "FDA had already asked Congress to create a risk-based expedited IND pathway" before TrialBlazer's launch (www.cooley.com), and Ropes & Gray describes it as an "optional, risk-based Expedited IND pathway for certain Phase 1 clinical trials" that would require Congress to amend the underlying statute (www.ropesgray.com).

Crucially, Ropes & Gray's own legal analysis concludes that "the descriptions of the two programs are markedly different, and it is not clear if" they are meant to converge (www.ropesgray.com). The RFI pilot is a proposed, FDA-run initiative involving voluntary QRI partnerships; the budget-request proposal would require new legislation from Congress and describes a structurally different, risk-based statutory pathway. Congressional interest in adjacent ideas predates TrialBlazer: Cooley notes Representative **Jake Auchincloss**'s May 2026 discussion draft proposed a similar "IND alternative pathway" modeled partly on Australia's system (www.cooley.com), and Senator **Bill Cassidy**'s February 2026 FDA reform roadmap "proposed that the agency launch a pilot program testing expedited clearance of low-risk Phase 1 studies" (www.cooley.com). Readers should treat any of these labeled "expedited IND" as potentially distinct initiatives until FDA or Congress clarifies otherwise.

Implementation Considerations and Process Changes

Because the Expedited IND pilot remains an RFI response, not a live program, **no sponsor can apply or enroll today**, and FDA has not published binding eligibility criteria, a start date, or a rollout timeline. What follows is drawn from the criteria FDA says it is "considering" in the RFI, framed as open questions rather than settled rules.

On the **QRI side**, the notice lists qualification factors FDA is weighing, including "comprehensive expertise across nonclinical (pharmacology/toxicology), clinical, and CMC disciplines" (www.govinfo.gov), sufficient clinical trial infrastructure to support Phase 1 studies, qualified leadership and personnel, and a track record in regulatory affairs. FDA states that after reviewing comments, learnings from the pilot could inform "QRI certification by FDA" down the line (www.govinfo.gov), implying a formal accreditation process is a possible, not certain, future step. A former FDA oncology division director quoted by trade press cautions that even a well-designed pilot cannot fix everything, arguing that "FDA is not the primary source of most delays in early phase clinical trials" (www.biospace.com), and a former FDA chief medical officer went further, stating "until we take care of the site issues, we're getting nowhere" (www.biospace.com), referring to IRB and site-contracting bottlenecks that sit outside FDA's direct control. A clinical-development executive interviewed separately cautioned that "regulatory speed does not necessarily equate to scientific success" (www.pharmavoice.com), attributing many delays to sponsor-side choices, noting that "the most punishing delays are self-inflicted by the industry through suboptimal protocol design" (www.pharmavoice.com).

TrialBlazer also includes actions adjacent to the pilot that sponsors should track separately. FDA's new **Phase 1 Contact Center** offers real-time responses to questions about clinical protocols, regulatory requirements, and other early-phase trial considerations (www.fda.gov), and the roadmap flags a potential future rulemaking that would require a single Institutional Review Board (**sIRB**) to serve as the "IRB of record" for multi-site studies (www.ropesgray.com), an idea one regulatory attorney suggested "should reduce duplicative review" (www.biospace.com). Separately, HHS's Office of Inspector General opened its own RFI as part of TrialBlazer, evaluating whether to update safe harbor regulations under the federal Anti-Kickback Statute (www.arnoldporter.com), a workstream unrelated to the IND pilot but worth tracking alongside it.

On the **sponsor readiness side**, likely considerations for companies evaluating whether to engage with a future pilot include:

- **Monitor potential QRI fees.** FDA expects that, following the pilot, sponsors will pay fees directly to QRIs and will not set or collect them. The RFI does not establish fees during the initial pilot, so sponsors should not assume a pilot-period fee structure unless FDA provides further details (www.govinfo.gov).
- **Retained IND ownership and FDA authority.** QRI input would be advisory, the sponsor would retain ownership of the IND submission, and FDA would retain regulatory decision-making authority.
- **No change to FDA's enforcement authority.** FDA retains its existing clinical-hold and inspection powers throughout, so participation does not reduce a sponsor's exposure to a hold if genuine safety issues surface.
- **Comparing the cost of a QRI against in-house capability.** Sponsors with strong internal nonclinical, clinical, and CMC teams may find limited marginal benefit, since the rolling-review advantage depends on using a QRI in the first place.

FDA has also posed its own open questions publicly, which sponsors and institutions weighing participation should track. The notice asks directly whether the design "could create inequitable access" (www.govinfo.gov) favoring larger, better-resourced sponsors who can afford QRI fees over smaller companies that cannot, and separately asks whether the pilot "could inadvertently compromise clinical trial participants' safety, scientific rigor, or ethical standards" (www.govinfo.gov). Arnold & Porter frames this as FDA genuinely asking the public "does the pilot program inadvertently compromise the safety of trial participants" (www.arnoldporter.com), underscoring that these are unresolved design questions, not settled protections.

Also relevant to implementation: FDA received "nearly 200 comments" on a separate, earlier RFI on AI-enabled early-phase trials that closed **June 29, 2026**, according to Cooley (www.cooley.com), a related but distinct initiative on FDA's use of AI in clinical trial oversight rather than the sponsor-facing IND pilot covered here.

Data Analysis and Evidence

Table 1 compares four established FDA expedited programs with the proposed Expedited IND pilot. It does not catalogue every FDA pilot program.

Program	Status as of August 2026	What It Targets	Key Mechanism
Fast Track	Established	Serious conditions, unmet medical need	More frequent FDA meetings and rolling review; FDA "will review the request and make a decision within sixty days" (www.fda.gov)
Breakthrough Therapy	Established	Drugs showing substantial improvement on a clinically significant endpoint	Intensive FDA guidance from early development; FDA "will respond to Breakthrough Therapy designation requests within sixty days of receipt" (www.fda.gov)
Accelerated Approval	Established (since 1992)	Serious conditions with unmet need	Approval based on a surrogate endpoint "reasonably likely to predict clinical benefit," instituted "in 1992" (www.fda.gov)
Priority Review	Established	The marketing-application review stage only	FDA's goal is action "within 6 months (compared to 10 months under standard review)" (www.fda.gov); explicitly "does not affect the length of the clinical trial period" (www.fda.gov)
Expedited IND Pilot (proposed)	**Request for information only; not established**	The pre-IND-to-first-in-human window specifically	Voluntary QRI partnership plus rolling submission review; original **July 22, 2026** deadline extended; comments due **August 24, 2026 at 11:59 p.m. ET** (www.fda.gov)

None of FDA's four established expedited programs is designed as a pre-IND-to-first-in-human pilot. Fast Track may be requested at the same time as, or after, an IND, and Breakthrough Therapy designation may be requested as early as Phase 1; both therefore operate outside the pre-IND window rather than uniformly at later stages (www.fda.gov) (www.fda.gov). Priority Review applies to marketing-application review, while Accelerated Approval addresses the evidentiary basis for approval rather than the speed of reaching Phase 1.

Separately, FDA's active **Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP)** supports CMC development for selected products under INDs with expedited clinical-development timelines and is scheduled to run through FY 2027 (www.fda.gov). It is distinct from both the four programs in Table 1 and the proposed QRI-based Expedited IND pilot.

Table 2 below assembles the process-timing benchmarks that HHS and FDA cite as motivating the initiative, alongside comparison figures for other countries where cited in the same sources.

Metric	Figure (as cited)	Source
U.S. average time, pre-IND meeting request to IND submission	**380 days**, range up to almost 700 days	HHS roadmap (hhs.gov)
U.S. typical wait for a pre-IND meeting	Up to **60 days**	HHS roadmap (hhs.gov)
U.S. regulatory IND review period	**30 days** from FDA receipt of the IND	fda.gov (www.fda.gov)
U.S. IRB review plus site contracting delay	Up to **13 months** before first patient enrollment	HHS roadmap (hhs.gov)
U.S. typical trial activation time	Frequently exceeds **160 days**	HHS roadmap (hhs.gov)
Australia, notification to trial start	Fewer than **70 days**	HHS roadmap (hhs.gov)
China, IND-to-trial-start commitment	Within **12 weeks** of submission	HHS roadmap (hhs.gov)
China's global share of registered clinical trials, 2024	**39%**, over 7,100 trials	HHS roadmap (hhs.gov)
Estimated time savings from phase-appropriate CMC guidance	**6 to 12 months** off overall development timeline	HHS roadmap (hhs.gov); Arnold & Porter (www.arnoldporter.com)

The pattern across Table 2 is that the delays HHS singles out, the pre-IND meeting queue, IRB and site contracting, and trial activation, sit largely outside the 30-day regulatory IND review clock, which is short and unchanged by the pilot. This matches the pilot's design, which targets the surrounding process rather than the regulatory review period, and explains why analysts, cited above, caution that its benefit depends on execution details FDA has not yet finalized, rather than on the RFI text alone.

On the animal-testing reform strand, HHS's own example of scale, that "the development of a monoclonal antibody may use hundreds of animals" (hhs.gov) under current nonclinical testing norms, illustrates the burden the risk-based nonclinical proposal is meant to reduce, building on FDA's already-issued streamlined nonclinical safety study guidance for monoclonal antibodies from December 2025.

Table 3 below lists the discrete TrialBlazer-related comment periods and their closing dates, since several run on different schedules and are easy to conflate.

Action	Comment Deadline	Docket / Source
Expedited IND Pilot Program RFI	Original **July 22, 2026** deadline extended; due **August 24, 2026** at 11:59 p.m. ET	Docket FDA-2026-N-4699 (www.fda.gov)
Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials	Initial Federal Register deadline: **July 24, 2026** (passed); FDA accepts guidance comments at any time	Docket FDA-2026-D-6539 (www.fda.gov)
AI-enabled early-phase trial oversight RFI (separate, earlier initiative)	**June 29, 2026** (closed); received nearly 200 comments	(www.cooley.com)

Action	Comment Deadline	Docket / Source
OIG Anti-Kickback Statute safe harbor RFI (separate workstream)	**August 24, 2026**	(www.arnoldporter.com)
Revised Draft Substantial Evidence Guidance	**September 22, 2026**	(www.cooley.com)

As of this report's **August 8, 2026** publication date, the Expedited IND pilot RFI remains open for comment through **August 24, 2026**; the FIH dose-selection guidance and AI oversight RFI comment periods have closed, while the OIG safe harbor RFI and Substantial Evidence Guidance windows remain open. FDA has not published a timeline for reviewing comments, finalizing pilot design, or naming initial QRIs; readers should treat any specific launch date encountered elsewhere with caution until FDA issues further notice. This sponsor-facing IND pilot is also a distinct initiative from FDA's separate work exploring AI-based real-time monitoring of ongoing clinical trials, which addresses trial conduct and safety surveillance after a study is already underway, not the pre-IND and first-in-human window discussed in this report.

Implications and Future Directions

If finalized in a form resembling the RFI, the Expedited IND pilot would insert a new intermediary, the QRI, between sponsors and FDA for a defined subset of Phase 1 programs. Institutions positioned to become QRIs, larger academic medical centers, established CROs, and specialized regulatory advisory firms, may be positioned to offer QRI services if FDA establishes the pilot, while smaller institutions may need time and resources to meet whatever qualification bar FDA ultimately sets. Second, sponsors will need to weigh any future QRI fees and engagement time against the potential benefit of parallel IRB work and a possible earlier "safe to proceed" notification; FDA has not established fees for the initial pilot. Third, because participation is voluntary and FDA retains full authority to issue clinical holds regardless of QRI involvement, the pilot does not change the underlying safety bar a Phase 1 program must clear; it changes who helps a sponsor prepare to clear it.

The FDA Phase 1 CMC webpage and nonclinical guidance strands do not depend on the pilot's outcome and may be useful resources for Phase 1 planning because they require no QRI relationship or fee arrangement. Sponsors preparing Phase 1 submissions may review FDA's phase-appropriate CMC expectations and draft streamlined nonclinical guidance for monoclonal antibodies, while continuing to plan under existing IND requirements.

Looking ahead, the most consequential open question is sequencing: whether FDA will finalize pilot design and name an initial QRI cohort, whether Congress will act on the FY2027 budget request's separate pathway, and whether the two efforts converge or remain parallel tracks, as Ropes & Gray's analysis suggests may currently be the case. Sponsors with active Phase 1 programs should monitor FDA's public docket and guidance pages directly, since no binding rule has been finalized on either proposal as of August 2026.

Frequently Asked Questions (FAQs)

What is FDA Operation TrialBlazer? Operation TrialBlazer is a department-wide HHS roadmap, announced **June 22, 2026**, coordinating FDA, the National Institutes of Health (**NIH**), the Advanced Research Projects Agency for Health (**ARPA-H**), and the HHS Office of Inspector General (**OIG**) around a shared goal of keeping early clinical

research based in the United States (www.ropesgray.com). It bundles several distinct FDA actions rather than a single rule.

What is the Expedited IND Pilot Program, specifically? It is a proposed, voluntary program under which sponsors could partner with potential Qualified Research Institutions, if FDA establishes the pilot, to develop and pre-review Phase 1 first-in-human protocols, potentially using a rolling submission process (www.govinfo.gov). As of August 2026, it remains a request for information, not an active program.

What other FDA actions are part of Operation TrialBlazer besides the IND pilot? Beyond the pilot, FDA identifies an updated Phase 1 CMC webpage, a Phase 1 Contact Center, QSP draft guidance, and revised draft guidance on substantial evidence of effectiveness as related TrialBlazer actions (www.fda.gov).

Has FDA finalized the Expedited IND pilot? No. FDA opened public comment on **June 24, 2026**. The original **July 22, 2026** deadline was extended; comments are due **August 24, 2026 at 11:59 p.m. ET** (www.fda.gov). FDA has not published a decision, launch date, or list of eligible institutions.

How does the current IND process work? A sponsor submits an IND containing nonclinical, CMC, and clinical protocol data. Unless FDA places the investigation on clinical hold, the IND becomes effective **30 days** after FDA receives the application; it may also become effective earlier if FDA notifies the sponsor that the clinical investigations may begin (www.fda.gov).

Will the pilot change the 30-day IND review clock? No. FDA's notice states that the 30-day regulatory IND review clock begins only after submission of all IND components (www.govinfo.gov); the pilot targets the surrounding process, not the regulatory review period.

Who would be eligible to become a Qualified Research Institution? FDA has proposed considering academic medical centers, healthcare networks, contract research organizations, and regulatory advisors (www.govinfo.gov), but has not published final qualification criteria or a certification process.

Does the pilot affect Phase 2 or Phase 3 trials? Not directly; it targets the pre-IND-to-first-in-human window. TrialBlazer separately includes revised draft guidance on the substantial-evidence standard for later-stage approval, for which FDA lists a **September 22, 2026** comment deadline (www.fda.gov).

Is this the same as the "expedited IND pathway" FDA asked Congress for? No. That is a separate, statutory proposal in FDA's FY2027 budget request, which Ropes & Gray describes as "markedly different" from the RFI pilot (www.ropesgray.com).

Conclusion

For sponsors and institutions, near-term planning can include reviewing FDA's updated Phase 1 CMC webpage and draft streamlined nonclinical guidance for monoclonal antibodies, both independent of the pilot's fate. The CMC webpage provides resources and clarifies phase-specific requirements; the draft guidances are nonbinding statements of FDA's current thinking and do not change existing IND requirements. Sponsors should continue to prepare INDs under existing requirements while monitoring the pilot and the separate statutory proposal. Sponsors

with Phase 1 programs in development should check FDA's public docket for Docket No. FDA-2026-N-4699 and FDA's TrialBlazer-related guidance pages directly for the current status before making planning assumptions based on any single secondary source, including this report.
