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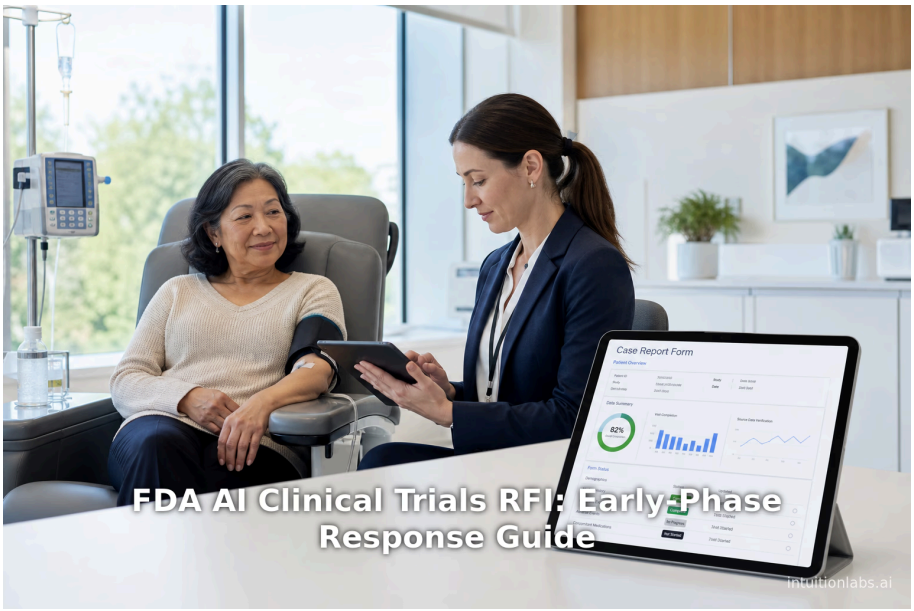
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FDA AI Clinical Trials RFI: Early-Phase Response Guide

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Executive Summary

The U.S. Food and Drug Administration (FDA) has launched an ambitious initiative to integrate artificial intelligence (AI) and real-time data into early-phase clinical trials, aiming to accelerate drug development while preserving safety and scientific rigor. In April 2026, FDA published a **Request for Information (RFI)** announcing a pilot program to **"AI-Enabled Optimization of Early-Phase Clinical Trials"**, with comments originally due May 29, 2026 and later extended to June 29, 2026 (www.federalregister.gov) (regulations.justia.com) (advocacy.sba.gov). Early-phase trials (Phase 1 and early Phase 2) are widely regarded as a bottleneck in drug development—characterized by high uncertainty, small patient populations, and protracted timelines (regulations.justia.com) (winbuzzer.com). The FDA's goal is to explore how AI-driven

methods and real-time data feeds can improve trial efficiency (e.g., speed up enrollment and decision-making), enhance safety monitoring, optimize dose selection, and enable more informed go/no-go decisions between phases, all **“while maintaining FDA’s rigorous scientific and regulatory standards and promoting trustworthy AI systems”** (regulations.justia.com).

This report provides an **in-depth analysis and practical guide** for stakeholders preparing or reviewing responses to the RFI, whose comment period closed on June 29, 2026 after FDA extended the original May 29, 2026 deadline by 30 days. We begin with background on the challenges of early-phase trials and the potential of AI technologies (including case study examples), then unpack the FDA’s pilot program objectives and questions. We examine the key focus areas solicited by the RFI—such as trial scope, participant and technology selection, collaborative models, operational structure, and evaluation metrics—and highlight evidence and expert perspectives on each. Throughout, we emphasize data-driven arguments and cite relevant research, regulatory guidance, and real-world examples. We also discuss safeguards and trustworthiness issues (e.g. AI model validation, transparency, bias mitigation) critical to any AI-driven clinical program, referencing the FDA’s alignment with the NIST AI Risk Management Framework (AI RMF) (regulations.justia.com) (www.fda.gov).

Key Findings

- **Clinical Trial Bottleneck**: Historically, only a small fraction of investigational drugs advance from Phase 1 to approval (around 14% on average (cen.acs.org)), with cancer agents much lower. Roughly half of the time between Phase 1 completion and regulatory submission is “dead time” spent on paperwork and data transfer (www.axios.com). FDA Commissioner Makary says that “key data signals can take years to reach the FDA” and that the lag “can delay regulatory decisions unnecessarily and slow down the drug development timeline” (www.fda.gov).
- **AI Opportunities**: AI and modern data tools can address specific early-phase challenges. For example, machine learning can dramatically accelerate patient screening (NIH’s TrialGPT cut screening time by ~40% without loss of accuracy (www.fiercebiotech.com)), improve patient stratification and biomarker analysis, optimize adaptive trial designs, and support dose-escalation decisions. FDA identifies a broad suite of AI use cases (Table 1) including *patient recruitment, dose optimization, safety surveillance, adaptive design evaluation, biomarker validation, and go/no-go decision support* (regulations.justia.com). Simulation and “ in silico” trials using AI can even generate virtual control cohorts to increase effective sample size (arxiv.org).
- **Proof-of-Concept Success**: In Spring 2026, FDA collaborated with AstraZeneca and Amgen on live pilot trials (TRAVERSE and STREAM-SCLC) where de-identified patient data (safety events, tumor responses, etc.) were streamed to FDA in real time via a secure cloud platform (Paradigm Health) (content.govdelivery.com) (winbuzzer.com). These trials demonstrated feasibility: FDA reviewers received and validated signals (e.g. fevers, tumor shrinkage) within days rather than months (content.govdelivery.com) (winbuzzer.com). Press reports quote FDA’s Chief AI Officer describing an aspirational opportunity to **shave as much as 20–40% off overall trial time**, and report ~$120 million in

annual cost savings (reallocated to re-hire research staff) (winbuzzer.com) (www.axios.com). The RFI frames the pilot as proceeding “while maintaining FDA’s rigorous scientific and regulatory standards and promoting trustworthy AI systems” (govinfo.gov).

- **Regulatory Framework & Trust**: FDA emphasizes **trustworthy AI** principles (validity, accountability, explainability, fairness, privacy) in line with NIST’s AI RMF (regulations.justia.com) (pmc.ncbi.nlm.nih.gov). A January 2025 FDA draft guidance outlines a risk-based “ credibility framework” for AI models supporting regulatory decisions (www.fda.gov). Respondents should address data governance, data privacy/protection, bias mitigation, and model transparency. As an EU perspective notes, AI models often “inherit the biases embedded in historical data” (pmc.ncbi.nlm.nih.gov), so robust safeguards (e.g. demographic performance checks, explainability tools) are required.
- **Metrics for Success**: The RFI solicits input on measurable outcomes. FDA categorizes evaluation into qualitative and quantitative metrics across domains (Table 2): **Trial efficiency** (e.g. time to enrollment/completion, throughput); **decision quality** (e.g. concordance of AI-assisted vs. traditional go/no-go decisions, reduced late-stage failures); **safety/data integrity** (e.g. time to adverse event detection, data completeness); **AI performance** (e.g. model accuracy, robustness, concept drift); and **trust** (e.g. evidence of model validity, transparency, explainability) (regulations.justia.com). Respondents can suggest specific measures (e.g. percentage reduction in timeline, error rates) and study designs (concurrent controls, simulations) to evaluate pilot outcomes.
- **Implications for Stakeholders**: Faster, more efficient trials could accelerate patient access to therapies and reduce costs, benefiting biopharma, patients, and the healthcare system. Industry leaders (e.g. Amgen, AstraZeneca) and patient advocates have broadly praised the initiative (www.hhs.gov) (www.axios.com). However, stakeholders must also consider new responsibilities: e.g. codifying AI within trial protocols, investing in interoperable data infrastructure, and engaging patients about data use. Ensuring inclusivity (rare disease and underrepresented populations) in pilot selection is critical to avoid embedding inequities. Overall, the RFI/pilot is a proactive attempt to shape a “continuous” trial paradigm, rather than reactively regulate only after AI becomes pervasive.
- **Response Guidance**: To craft an effective response, stakeholders should thoroughly address each RFI area with evidence and specifics. This means (a) framing *which* trial scenarios and AI technologies your organization can support, (b) proposing how participants and use-cases would be selected (e.g. therapeutic area expertise, technology readiness), (c) outlining collaboration models (e.g. sponsor-vendor-FDA consortium), (d) detailing operational needs (data systems, cloud platforms, regulatory engagement), and (e) defining clear metrics for pilot evaluation. Comments were required to include the docket number (FDA-2026-N-4390); the period closed at 11:59 p.m. ET on June 29, 2026, after FDA extended the original May 29, 2026 deadline (extension notice: www.federalregister.gov; original notice: regulations.justia.com). Responses should avoid confidential information in the body and may use written submissions for proprietary details (regulations.justia.com) (legiseye.com). Citing research, pilot data, or precedents will strengthen recommendations. Note (November 2026): the comment period has closed, so the respondent advice below is best read as retrospective analysis; this article does not confirm whether FDA has since published selection criteria or announced pilot participants, so check FDA’s website for current status.

This report delves into each of these topics in detail, with extensive citations from FDA sources, peer-reviewed studies, industry analyses, and expert commentary. Our goal is to equip stakeholders—pharmaceutical and biotech companies, clinical research organizations, technology vendors, clinician investigators, patient groups, and others—with the context and guidance needed to formulate data-driven, constructive feedback. By aligning stakeholder input with FDA's criteria, comments submitted by the deadline can help shape a successful pilot that accelerates the development of safe, effective new therapies.

Introduction and Background

The development of new drugs is an inherently lengthy and costly endeavor. Early-phase (Phase 1 and often Phase 2a) trials play a crucial gatekeeping role, assessing safety, dosing, pharmacokinetics, and early signs of efficacy. These studies often involve small numbers of patients, frequently those in fragile health (e.g. oncology or rare disease cohorts), and perforce proceed cautiously. Decision-making is challenging: selecting a safe initial dose and deciding when to halt or escalate requires careful judgment under uncertainty. Historically, most experimental drugs fail in later stages: only about **13.8%** of compounds entering Phase 1 eventually gain approval (cen.acs.org) (even lower for oncology, ~3.4% (cen.acs.org)), underscoring inefficiencies in the pipeline.

Several factors make early-phase trials a "bottleneck" in drug development. FDA highlights that such trials are "often characterized by high uncertainty, limited patient populations, and inefficient decision-making processes" (regulations.justia.com). After trials produce data, results traditionally flow slowly: investigators pass information to sponsors, who conduct analysis (sometimes taking weeks or months), and only then submit reports to regulators. FDA Commissioner Makary notes that decades of trial practice have included substantial lag: roughly **45%** of the time between a Phase 1 trial and an FDA application is "dead time" consumed by paperwork and data transfers (www.axios.com). He explains that in the conventional model, critical data signals can "take years to reach the FDA," unnecessarily delaying regulatory decisions (content.govdelivery.com) (www.axios.com). The end result is a protracted path to market: conventional wisdom holds that new therapies can take **10–12 years** to progress, a timeline the FDA now challenges (www.axios.com).

Compounding these delays are operational inefficiencies. Broadly, "overloaded with data, yet starved for insight," the industry often struggles to distill useful signals from the vast information generated during trials. Patients eligible for trials may go unrecruited, sites may overrun on safety monitoring, and sponsors may err on the side of conservatism in dose escalation to avoid adverse events. Each of these factors can contribute to prolonged studies and higher costs (estimates suggest upwards of $2–3 billion and well over a decade per new drug (regulations.justia.com) (cen.acs.org)).

Against this backdrop, new computational tools offer promise. Artificial intelligence (AI)—encompassing machine learning (ML), deep learning, and related data-driven techniques—has begun to transform many scientific fields, including drug development and clinical research. In particular, AI can extract insights from complex and heterogeneous data (genomic, imaging, electronic health records, etc.) and continuously learn from new inputs. In the late 2010s and early 2020s, pharmaceutical and technology companies started piloting AI for tasks such as patient matching, adaptive trial simulations, and automated image or video analysis. For example, recent work developed an AI model ("TrialGPT") to match patients to clinical trials using large

language model techniques; it achieved screening matches almost as accurately as human experts while **cutting screening time by 40%** (www.fiercebiotech.com). Other research projects have shown that ML-driven simulation ("in silico" trials) can create virtual patient cohorts and even predict trial success rates, potentially reducing the need for larger control arms (arxiv.org). In dose-ranging studies, methods like deep reinforcement learning have demonstrated potential to find optimal escalation rules for phase 1 oncology trials (arxiv.org).

Regulators worldwide have taken note of these trends. The 21st Century Cures Act (2016) and other legislative mandates explicitly encourage the use of real-world evidence and innovation in trial methods. Within the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), there has been a growing model-informed drug development (MIDD) effort (e.g. the 2018 MIDD Pilot Meetings Program (regulations.justia.com)). Most recently, FDA established an Artificial Intelligence and Machine Learning (AI/ML) program and even named a Chief AI Officer, reflecting agency leadership support. In January 2025, the FDA issued a draft guidance ("Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making") which lays out a **risk-based credibility framework** for AI models used in products, underscoring topics like model validation, context of use, and transparency (www.fda.gov).

Building on this context, in April 2026 the FDA took two major steps: it publicized two operational **proof-of-concept real-time trials** (with AstraZeneca and Amgen, as discussed below), and it issued an RFI seeking public input on a broader **pilot program for AI-enabled early-phase trials** (content.govdelivery.com) (winbuzzer.com). The RFI frames a vision of *real-time* trial oversight: rather than waiting for bulky final reports, FDA reviewers might see key safety and efficacy signals continuously as the trial unfolds, potentially speeding decisions while still respecting safety. Successfully done, this could help close the current "continuous trials" gap, where discrete phases create downtime (from data lock, analysis, protocol drafting, etc.) between studies (content.govdelivery.com) (www.hhs.gov).

This report will examine all aspects of this initiative. We cover the technological and statistical underpinnings of AI in trials, regulatory considerations and past precedents (including the parallels to MIDD and adaptive designs), the design of the proposed pilot program (scope, structure, evaluation), and the real-world pilot experiences already underway. We include concrete data, case examples, and expert perspectives from industry, academia, and regulators. Finally, we provide guidance on responding to the RFI: advising on how to address each of the FDA's requested topics with evidence and specificity. Our emphasis throughout is on rigorous evidence and balanced analysis, to help stakeholders understand the RFI and what thorough, constructive comments looked like before the comment period closed on June 29, 2026 (extended from May 29, 2026) (regulations.justia.com) (legiseye.com).

AI in Early-Phase Clinical Trials: Opportunities and Use Cases

AI technologies span a diverse set of tools (machine learning, neural networks, natural language processing, etc.) able to process complex biomedical data. In early-phase trials, such tools can be applied at multiple stages to streamline operations and improve decision-making. Below, we highlight major AI use cases, supported by evidence and examples, that inform FDA's initiative. These use cases are summarized in **Table 1**.

- **Patient Recruitment and Selection**: Enrolling appropriate patients is often a time-consuming bottleneck. AI can analyze electronic health records (EHRs), genomic and phenotypic data, and trial protocols to identify eligible candidates much faster than manual screening (www.fiercebiotech.com). NIH researchers developed TrialGPT, a large-language-model-based tool, which matched patients to trials with 87.3% accuracy (near human levels) and **sped up screening by ~40%** without loss of precision (www.fiercebiotech.com). AI also enables more nuanced patient stratification: for example, by integrating diverse data sources, AI can help identify subpopulations likely to benefit (responders vs. non-responders) or who meet complex inclusion criteria (e.g. rare biomarkers). Improved recruitment not only accelerates trials but can enhance statistical power by optimizing cohort composition.
- **Dose Optimization and Escalation**: In Phase 1 oncology trials, determining safe and effective dose-escalation schemes is critical. Traditional designs (e.g. 3+3) are often conservative and may expose many patients to subtherapeutic or intermediate dose levels. AI can enable **model-informed designs** where real-time patient response data (toxicity, pharmacodynamics) feed reinforcement-learning or Bayesian algorithms to suggest next dose cohorts. FDA's RFI says the pilot program aims to explore how AI and data science can help facilitate dose selection decisions. Over time, validated AI-driven designs could replace static escalation rules, accelerating the path to effective doses.
- **Adaptive Trial Design and Interim Decision-Making**: Early-phase studies increasingly use adaptive elements (e.g. stopping rules, dose adjustments, expansion cohorts). AI augments this by continuously analyzing accumulating data. For instance, an AI system could detect signals in pharmacokinetics, biomarkers, or adverse events and recommend protocol adjustments mid-study. This might include rebalancing cohorts or adaptively re-estimating sample sizes. The FDA RFI specifically mentions facilitating early go/no-go decisions (e.g., a regulatory decision as to whether a Phase 1 study may proceed) as a goal (regulations.justia.com). If an AI model, trained on historical trial outcomes, predicts that further investment won't yield success, sponsors might end development earlier. Conversely, emerging hints of efficacy could be acted upon quickly, accelerating go-forward programs. A key advantage is shortening "decision cycles" – rather than waiting for end-of-phase data analysis, decisions can be based on live-model predictions. As one analyst notes, this "enables the FDA to make decisions faster …all while preserving the foundational requirements of safety and data integrity" (www.hhs.gov).
- **Safety Monitoring and Pharmacovigilance**: Early human trials may reveal unforeseen adverse events. Traditionally, trial sites record events and eventually compile them for review. AI can continuously monitor multi-site data feeds to flag safety signals earlier. For example, real-time algorithms could analyze EHRs or patient portals for symptom reports, flagging trends that suggest a dose-related toxicity. The pilot uses Paradigm Health's platform to detect events in the TRAVERSE trial almost in real time (winbuzzer.com). Encouragingly, the pilot has already demonstrated the technical feasibility of this: investigators validated safety signals (like fevers or lab anomalies) within days (winbuzzer.com). In a high-stakes context, this means FDA reviewers and sponsors can intervene more promptly (e.g. modifying dose or pausing enrollment) than in conventional trials. Stakeholders must ensure such AI systems maintain patient privacy and data security while scanning sensitive health data across sites.

- **Biomarker and Endpoint Validation**: Phase 1 trials often collect biomarker data (genetics, imaging, blood markers) that are weakly correlated with outcomes due to small N. AI can help validate surrogate endpoints or identify novel biomarkers during the trial. For example, machine vision applied to imaging might quantify treatment response faster and more reproducibly than radiologist scoring (winbuzzer.com). AI-based pattern recognition could suggest new endpoints (e.g., digital pathology or functional biomarkers) for future phases. The FDA RFI explicitly mentions AI's potential to *"improve biomarker assessment"* and *"improve biomarker-based patient selection/stratification"* (regulations.justia.com). Real-world evidence also suggests machine learning can uncover phenotype subgroups aligned with drug response, which is particularly valuable in early trials with heterogeneous responses.
- **Data Quality and Integrity**: AI can help ensure high-quality data collection. Automated error-checking algorithms can detect data entry anomalies or outliers in real time, prompting immediate query resolution. AI-driven central monitoring can spot site-level irregularities (e.g. unusually low variability in vital signs from one site). In real-time trials, this meta-monitoring becomes continuous: as Paradigm Health standardizes and validates incoming data feeds, it reduces the risk of late discovery of data discrepancies (a notable issue in past multi-site trials (winbuzzer.com)). Moreover, AI models themselves can include measures of confidence or uncertainty to signal when data is insufficient for reliable predictions.
- **Simulated and In Silico Trials**: Although more exploratory, one emerging AI use is to run virtual arms or simulations supplementing actual trials. AI could model a "digital twin" of patient physiology and simulate trial outcomes under different scenarios, informing trial design (heuristic generation of control data, power calculations). A 2022 review notes that **AI-driven in silico trials** can *"increase the case group size by creating virtual cohorts as controls"*, optimizing design and predicting success rates (arxiv.org). For the FDA pilot, simulation studies may inform comparative analyses (e.g. using historical controls or synthetic data), as requested in the RFI's evaluation section (regulations.justia.com). While not a replacement for human data, such tools can refine hypotheses and reduce reliance on large control arms in rare diseases.

Table 1. AI Use Cases in Early-Phase Clinical Trials. Examples and evidence of how AI and data science can support trial optimization in various domains (regulations.justia.com) (www.fiercebiotech.com) (winbuzzer.com) (arxiv.org).

Use Case	Applications & Benefits	Example / Evidence
Patient recruitment	Accelerate matching and enrollment by scanning health records, trial registries, biomarkers; identify eligible candidates faster.	NIH "TrialGPT" matched patients to trials with ~87% accuracy, speeding screening by **40%** (www.fiercebiotech.com). Likely much higher throughput vs. manual.
Dose optimization	Adaptive, model-based dose-escalation: AI (e.g. reinforcement learning) suggests next dose levels based on incoming safety/PK signals, improving MTD estimation.	FDA's RFI lists dose selection among the areas the pilot would explore.

Use Case	Applications & Benefits	Example / Evidence
Safety monitoring	Real-time detection of AEs: ML algorithms flag safety events (labs, vitals, EHR symptoms) across sites; faster signal detection and response than periodic review.	In FDA pilots, safety events from AstraZeneca's trial were validated and reviewed in days (winbuzzer.com) (rather than months under usual process).
Adaptive design support	Continuous interim analysis: AI evaluates accumulating data to support early cohort expansions, trial extensions, or stops, without losing statistical validity.	Adaptive designs supplement AI predictions; FDA's RFI specifically notes enabling **earlier go/no-go** decisions with AI (regulations.justia.com).
Biomarker analysis	Automated interpretation of imaging/omics: AI uncovers response biomarkers or validates novel endpoints from Phase 1 data (e.g. tumor shrinkage metrics, digital assays).	AI-assisted image analysis or digital biomarkers can validate endpoints more quickly. Paradigm's pilot uses tumor response signals in real-time stream (winbuzzer.com).
Data standardization/ QA	On-the-fly data curation: AI ensures data are clean and consistent (e.g. anomaly detection in datasets, continuous central monitoring).	Paradigm's platform ingests and standardizes sponsor data feeds, exposing only verified, de-identified signals to FDA (winbuzzer.com).
In silico simulations	Virtual control arms: AI generates synthetic participants to augment small sample sizes; simulates trial variations for planning.	Reviews show AI-driven simulations can create virtual cohorts and predict success rates, optimizing trial design (arxiv.org).

Each of the above AI use cases can contribute to the pilot's objectives of **speed, efficiency, and decision quality** (regulations.justia.com). For example, improved recruitment and adaptive dosing truncate enrollment and evaluation times; real-time safety scanning narrows "decision lag" and prevents costly late-stage failures; and advanced biomarker analytics may highlight early efficacy signals that justify accelerated development. Importantly, all AI applications must be embedded in rigorous validation. The FDA emphasizes "trustworthy AI" – systems that are valid, safe, explainable, and fair (regulations.justia.com) (pmc.ncbi.nlm.nih.gov). Stakeholders responding to the RFI should cite evidence (e.g. prior studies, pilot data) of each AI approach's performance and reliability in clinical contexts.

FDA's AI Pilot Program and RFI: Goals and Structure

On April 29, 2026, the FDA officially **announced** the proposed pilot program and issued a Federal Register RFI outlining its scope (regulations.justia.com) (content.govdelivery.com). This pilot falls under FDA's initiative on *real-time clinical trials*, which aims to fundamentally reshape how data flows from trial sites to regulators (see sidebar). The RFI is canvassing stakeholder input on how best to design and implement this pilot. Below we detail the program's *proposed objectives*, *guiding principles*, and *questions* that FDA is asking.

Objectives of the Pilot

The overarching objective is to explore how AI-enabled tools and data science can **improve efficiency, speed, and decision-making quality in early-phase trials**, while maintaining safety and scientific standards (regulations.justia.com). The FDA's summary explicitly states that the pilot should:

- **Improve trial efficiency and speed** (e.g. shorten timelines, enrollment) (regulations.justia.com) (www.axios.com).
- **Enhance safety monitoring**, enabling earlier detection of adverse events and participant risks (regulations.justia.com) (winbuzzer.com).
- **Facilitate dose selection decisions**, supporting adaptive (data-driven) escalation schemes (regulations.justia.com).
- **Enable more informed go/no-go decisions** between phases, by leveraging aggregate data for earlier evaluation (regulations.justia.com).

These aims align with FDA's broader goals: accelerating drug development to bring effective therapies to patients sooner, as articulated by Commissioner Makary ("Today is a milestone day for us to challenge the assumption that it takes 10 to 12 years for a new drug to come to market" (www.axios.com)) and Chief AI Officer Walsh (who described real-time trials as "potentially transformative for the clinical trials ecosystem" (www.fda.gov)). Notably, the FDA is not simply reducing oversight: the agency intends these processes to preserve safety and data integrity even as trial durations shrink (www.axios.com) (winbuzzer.com). In practice, the pilot will test *how* to integrate live data feeds and AI analyses in an FDA review workflow.

Guiding Principles: Trustworthy AI and RMF Alignment

Trust is paramount. The RFI announces that the pilot "will be guided by principles aligned with the National Institute of Standards and Technology (NIST) AI Risk Management Framework (AI RMF)" (regulations.justia.com). These principles include ensuring AI systems are **valid, safe, secure, accountable, explainable, privacy-protective, and fair**. In other words, the pilot must not compromise fundamental human-subject protections even as it uses advanced technology (regulations.justia.com) (pmc.ncbi.nlm.nih.gov). FDA has similarly emphasized in guidance that sponsors should establish a **risk-based credibility assessment** for AI models, demonstrating the model's validity for its context of use (www.fda.gov).

Respondents should therefore be prepared to discuss safeguards: e.g., how datasets will be curated and labeled; how models will be tested for accuracy and bias; how negative outcomes will trigger reviews; and how decisions made with AI will be documented. For instance, FDA states that the pilot would promote trustworthy AI systems. Mechanisms for explainability (e.g. feature attribution, rule-based checks), privacy protections (secure de-identification, encryption), and equitable performance (ensuring all demographic groups are represented) will be central to FDA's trust considerations.

RFI Question Framework

FDA's RFI is structured into two main sections: **Pilot Program Design** (Section II.A) and **Evaluation Metrics and Success Criteria** (Section II.B). The notice invites comments on a series of detailed questions under each heading. Key question categories include:

- **Scope and Focus**: Which trial settings and AI applications to prioritize. For example, FDA asks *"Which trial types or trial issues might benefit most from the application of AI (e.g., first-in-human, oncology dose escalation, rare disease trials)?"* (regulations.justia.com). Stakeholders can suggest concentrating

on therapeutic areas where limited patients or rapid data changes make real-time review valuable. FDA also queries whether the pilot should target specific AI use cases (e.g. patient recruitment vs. safety monitoring) and whether to focus on particular domains or remain disease-agnostic (regulations.justia.com).

- **Participant and Sponsor Selection**: Criteria for choosing participants (sponsors, trial sites, vendors). Questions include: What factors should guide FDA's selection of sponsors/technologies (experience, infrastructure, trial readiness)? How to ensure diversity among participants (big pharma vs. small biotech, different therapeutic areas)? (regulations.justia.com). Early-phase trials might involve smaller companies or academic centers; respondents should advise on an inclusive strategy (e.g. include rare disease consortia) and on balancing technical maturity (ensuring pilots are feasible) with representativeness.
- **Collaboration Models**: Partnerships and governance. The RFI asks about effective partnership models (e.g. sponsor–subcontractor–FDA consortia, multi-stakeholder coalitions) and how FDA can foster *pre-competitive* collaboration and data sharing (regulations.justia.com). Respondents can propose frameworks (perhaps akin to Project Data Sphere or TransCelerate initiatives) where de-identified data and best practices are shared. Importantly, the RFI highlights involving patient groups and investigators in AI governance–respondents should articulate how community and clinician input should shape AI roles and oversight (regulations.justia.com).
- **Operational Structure and Support**: What support the FDA will provide and what infrastructure pilots need. For instance, what regulatory or technical guidance (pre-sub meetings, templates) should FDA offer? What secure data environment, cloud architecture, or "data firewalls" are needed to share live trial data? How to handle participants with varying AI readiness (e.g. multiple CROs with different systems)? (regulations.justia.com). This is an area for detailed proposals: companies may outline necessary IT systems, propose common data standards, or request "safe harbor" feedback protocols.
- **Timeline and Milestones**: Expectations for pilot duration and checkpoints. The RFI asks for thoughts on the overall timeline (perhaps a few months vs. a year) and key interim milestones (e.g. enrollment goals, interim safety analyses) (regulations.justia.com). FDA itself signaled a rapid timeline: comments were originally due May 29 (later extended to June 29), with final pilot criteria planned for July and selections for August (outcomes of those later steps are not confirmed here) (content.govdelivery.com) (winbuzzer.com). Respondents might suggest reasonable trial durations (e.g. 6–12 months per study) and interim assessments that balance quick insights with scientific rigor.
- **Knowledge Sharing**: Plans for disseminating lessons. The agency is keen on public transparency, subject to confidentiality. Questions include how to capture and share lessons learned, and how to remain open while protecting proprietary data (regulations.justia.com). Effective responses may propose workshops, white papers, or data-sharing consortia, and discuss redaction strategies to balance transparency with competitive interests.

FDA has also laid out **detailed questions on evaluation** (Section II.B, see Table 2). Stakeholders should provide input on each category of metrics (e.g. Trial Efficiency, Decision Quality, Safety, AI Performance, Trust, Comparative Evaluation, Qualitative Outcomes) (regulations.justia.com). For example, under "Trial Efficiency,"

FDA asks how to measure reductions in *time to initiation, enrollment, completion, or Phase 1→Phase 2 transition* (regulations.justia.com). Under "Decision Quality," they ask how to quantify improvements in go/no-go decision-making (e.g. concordance between AI-supported and traditional decisions) and decreases in late-stage trial failures (regulations.justia.com). Respondents should suggest concrete metrics (e.g. percentage reduction in enrollment time, error rates of AI predictions, statistical comparison methods) and discuss study designs (e.g. using matched controls or simulations) to evaluate these outcomes. (regulations.justia.com).

Table 2 below summarizes these evaluation categories and illustrative metrics; detailed discussion follows in a later section. (Notably, the RFI repeatedly references the NIST AI RMF under "Trustworthiness," seeking ways to measure fairness, robustness, and explainability (regulations.justia.com).)

Table 2. Pilot Evaluation Categories and Example Metrics. FDA solicits input on metrics to evaluate pilot outcomes across multiple domains (regulations.justia.com). Stakeholders should propose specific measures per category.

Category	Key Evaluation Questions (from RFI)	Example Metrics/Approaches
Trial Efficiency & Speed	How to measure improvements in trial speed (time to study start, enrollment, completion, etc.) (regulations.justia.com).	Reduction in days between key milestones (e.g. site activation, first patient in, last patient out); enrollment rate increase; shorter gaps between Phase 1 and Phase 2 initiation (regulations.justia.com).
Decision Quality	How to evaluate quality and timeliness of go/no-go decisions (FDA and sponsor) (regulations.justia.com). Compares AI-supported vs. traditional actions.	Concordance rate between AI-recommended decisions and historical decisions; accuracy of predictions vs. actual outcomes; reduced number of candidates failing in Phase 2 due to upstream errors (regulations.justia.com).
Safety & Data Integrity	Metrics for safety monitoring (time to detect signals) and data quality (regulations.justia.com).	Time from event onset to notification; adverse-event rates or protocol deviations before/after AI; measures of data completeness/consistency across sites (regulations.justia.com).
AI System Performance	Appropriate metrics for AI accuracy, robustness, generalizability (regulations.justia.com).	Model accuracy (sensitivity, specificity, AUC) on hold-out data; robustness to noise/drift; performance across sub-populations and sites (regulations.justia.com).
Trustworthiness (NIST RMF)	Evidence supporting AI validity, risk mitigation, explainability, fairness (regulations.justia.com).	Quantitative fairness metrics (e.g. equalized odds across demographics); measures of model explainability (e.g. percent of decisions with clear feature attribution); results of independent validation studies (regulations.justia.com).
Comparative Evaluation	Appropriate comparators (historical controls, non-AI trials, simulations) and accounting for design differences (regulations.justia.com).	Proposed study designs: e.g., run concurrent control arms without AI; use historical databases as a comparison; apply simulation studies. Statistical methods to control for trial design differences (regulations.justia.com).
Qualitative Outcomes	Measuring stakeholder trust, usability, and practical feasibility (regulations.justia.com).	Surveys of investigator/FDA confidence; usability scores for AI tools; documented changes in workflow or procedure; case studies of implementation challenges (regulations.justia.com).

The above categories reflect the RFI's explicit structure. Responders should frame their feedback around these and provide reasoned answers to the numbered questions (e.g., 1(a), 2(b), etc.). In particular, linking proposed metrics to pilot objectives (e.g. citing literature on how timely safety detection reduces patient risk)

will be persuasive.

Regulatory and Notification Details

The RFI (Docket No. FDA-2026-N-4390) was published in the Federal Register (91 FR 23100) on April 29, 2026 (regulations.justia.com). Comments could be submitted electronically via *Regulations.gov* until **11:59 p.m. Eastern Time on May 29, 2026**; FDA later extended the comment period by 30 days, to June 29, 2026, and the period has since closed (regulations.justia.com). Respondents must include the docket number on submissions. FDA notes that comments will be publicly posted, so avoid including any personal or confidential business information in the public text. Proprietary data should be submitted in written/paper form with the sensitive portions clearly marked. For convenience, a summary of key dates is given in Table 3.

Event	Deadline/Date	Notes
Publication of RFI (Federal Register)	April 29, 2026	Federal Register Vol. 91, No. 82 (regulations.justia.com)
Comment Submission Deadline	June 29, 2026 (11:59 p.m. ET); originally May 29, 2026	Electronic via Regulations.gov; extended by FDA notice (federalregister.gov); original notice (regulations.justia.com); public docket
Final Pilot Criteria Announced	July 2026 (FDA's planned timeline; outcome not confirmed)	Per FDA press briefing timeline (content.govdelivery.com) (winbuzzer.com)
Pilot Selections Completed	August 2026 (FDA's planned timeline; outcome not confirmed)	Per FDA timeline (content.govdelivery.com) (winbuzzer.com)
Pilot Initiative Launch	Summer 2026 (tentative)	Following selection, pilots commence

Table 3. Key dates and milestones for the FDA RFI and pilot timeline (per FDA announcements) (regulations.justia.com) (content.govdelivery.com) (winbuzzer.com).

Case Studies and Real-World Examples

To illustrate possibilities and guide recommendations, we discuss recent and ongoing examples of AI and real-time data use in clinical trials. These real-world cases highlight both technical feasibility and operational considerations for the FDA pilot.

AstraZeneca and Amgen Real-Time Pilot (April 2026)

In late April 2026, the FDA announced the initiation of two **proof-of-concept real-time clinical trials**. The pharmaceutical companies AstraZeneca and Amgen collaborated with the FDA to stream trial data directly to regulators as the trials proceed (content.govdelivery.com) (winbuzzer.com). Specifically:

- **AstraZeneca's TRAVERSE (Phase 2)**: A multi-site study of a novel oncology therapy for treatment-naïve mantle cell lymphoma. Sites at MD Anderson Cancer Center and University of Pennsylvania participated (winbuzzer.com).

- **Amgen's STREAM-SCLC (Phase 1b)**: A trial in limited-stage small-cell lung cancer (winbuzzer.com).

For each trial, FDA engineers worked with sponsors to establish criteria for **real-time data reporting**. After trial initiation, AstraZeneca and Amgen began sending *de-identified trial data feeds* (e.g. dosing levels, adverse events, efficacy markers) through a secure cloud platform provided by Paradigm Health. The pilots were built on a shared infrastructure: in both cases, sponsor data were streamed into a common cloud environment, where FDA reviewers could see updates continuously (winbuzzer.com). This replaces the traditional flow (site→sponsor→FDA) with a direct site→FDA pipeline.

The results have been promising. According to FDA statements, the agency **has already received and validated live signals** from AstraZeneca's trial (winbuzzer.com). Marty Makary analogized the transformation vividly, saying regulators can now watch a patient's fever or tumor size **"in the cloud in real time"** (winbuzzer.com). In practical terms, this means FDA reviewers are no longer waiting months for a compiled report; instead, they see new safety or efficacy information within days. As the pilot article notes:

> "For sponsors, the practical change is that a regulator can flag a dose-response anomaly, an emerging adverse-event pattern, or an unexpected biomarker shift *inside the same week* the study site records it, instead of waiting for an end-of-phase data lock." (winbuzzer.com)

This capability dramatically accelerates oversight. Chief AI Officer Jeremy Walsh has said there is an opportunity to shave off as much as **20–40%** of overall trial time, while FDA states its intent to preserve safety standards (winbuzzer.com). In fact, WinBuzzer reports that FDA projected $120 million in annual savings (from faster reviews) that could be reinvested into hiring ~3,000 new review scientists (winbuzzer.com). Importantly, both Walsh and Makary emphasized that speed is not sought *at the expense of safety*. Walsh and others argue that with continuous data flow, *less* information (focused "signals" rather than raw bulk data) can suffice for confident decisions (winbuzzer.com) (www.axios.com). The pilot design leaves each trial's treatment protocol unchanged; only the data reporting and review process is altered (winbuzzer.com).

The scenario highlights several learnings for the broader RFI:

- A **cloud-based data infrastructure** (here, Paradigm Health) can securely ingest and standardize diverse trial data streams (winbuzzer.com). Paradigm validated that sponsors' data adhered to agreed schemas and then furnished FDA with sanitized "signals" without requiring locked datasets (winbuzzer.com). stakeholders can comment on similar infrastructure needs (e.g. data standards, API specifications) in their RFI responses.
- **Regulatory workflow changes**: Reviewers shift from periodic batch reviews to ongoing monitoring. In this pilot, FDA scientists could immediately evaluate events. Stakeholders should discuss how regulatory processes (e.g. labeling, safety committees) would adapt to continuous inputs. For instance, would the FDA convene safety reviews on an accelerated schedule? How would adverse events be adjudicated in real time?
- **Trial design choices**: FDA chose these particular trials for specific reasons. Both involved narrow, biomarker-driven populations and rapid response profiles (winbuzzer.com), making them "well suited to a feed that emphasizes signal density over data volume." In other words, both lymphoma and lung-cancer trials can quickly show effects (tumor shrinkage, biomarker change), so real-time monitoring is

especially informative. Respondents might consider this insight: pilots may start with trials where AI benefits are clearest (oncology, rare diseases with strong biomarkers, etc.) and later expand as experience grows.

- **Privacy and consent**: Public descriptions of the proof-of-concept trials do not detail their consent or privacy arrangements, so respondents should source those details to FDA, sponsor, or IRB documents. Commenters should discuss consent models and data governance frameworks to protect participants, especially if personal health updates are streamed.

This case study, supported by multiple news reports and FDA announcements (winbuzzer.com) (www.axios.com), provides concrete evidence that real-time AI-enabled trials are not just theoretical. Any RFI response should reference such examples where possible. For instance, one might note: “In FDA’s pilot, Paradigm Health’s platform successfully delivered validated trial signals to reviewers in days rather than months (winbuzzer.com), demonstrating feasibility of near-real-time oversight.” Citing these pilot results underscores confidence that the proposed AI systems can work in the real world.

Other Relevant Examples and Precedents

While the AstraZeneca/Amgen trials are the headline story, there are related developments worth noting:

- **Clinical Trial Data Integration Platforms**: Companies like Paradigm Health (in the pilot) and medical research networks (e.g. PCORI’s PCORnet) have been building platforms to aggregate de-identified trial and health data. For example, Paradigm Health touts its ability to analyze site-level electronic health records for trial signal detection and to relay them rapidly (www.hhs.gov). These systems illustrate how FDA and sponsors can collaborate on data infrastructure.
- **AI in Regulatory Context**: The FDA has previously run pilots using predictive models for regulatory purposes. (For example, CDER has explored AI to predict drug safety issues post-approval.) While not RCTs, these efforts show the agency’s growing familiarity with AI analytics.
- **Other Manufacturers and Trials**: Various pharmaceutical companies have experimented internally with AI in Phase 1. For example, NIH researchers evaluated the TrialGPT model on three cohorts of 183 synthetic patients and in a small clinician comparison on six patient summaries, reporting about 40% faster screening in that small comparison—not a CRO deployment or real-world result (www.fiercebiotech.com). Contract Research Organizations (CROs) may have relevant case studies.
- **International Efforts**: Regulatory agencies elsewhere (e.g. EMA, PMDA) have also signaled interest in AI. The EU AI Act (Regulation (EU) 2024/1689) is already in force and applies in phases; as published, obligations for high-risk AI under its Article 6(1), which covers AI in regulated products such as medical devices, apply from 2 August 2027. Early-phase AI tools may also fall under such regimes in the future, so multinational respondents should consider alignment.

Stakeholders may draw lessons from these experiences: e.g., how Paradigm handled schema validation (winbuzzer.com), or how NIH’s TrialGPT was validated on synthetic patient records (www.fiercebiotech.com). Including such citations (e.g. the Nature Communications study underlying TrialGPT (www.fiercebiotech.com)) can strengthen a response. In summary, case studies attest to both the **promise** of AI acceleration and the **work required** to implement it at scale. The RFI responses should be grounded in this reality.

Key Issues for Pilot Design

Building on the context and use cases above, we now address the main design considerations that the RFI raises. We group them under the RFI's question categories, summarizing important factors and giving analysis for potential responses.

1. Scope and Focus of the Pilot

The FDA seeks comments on *which trial contexts and AI use cases to include*. The underlying question is: **where can AI add the most value?** Possible considerations include:

- **Trial Phase and Therapeutic Area**: Early-phase covers diverse scenarios: first-in-human safety studies, dose-ranging oncology trials, rare disease cohorts, etc. FDA specifically asks whether the pilot should concentrate on certain areas (e.g., oncology, neurology) or be broad. Respondents should evaluate trade-offs. For example, oncology trials — as chosen in FDA's pilot — often have predictable biomarkers and urgent timelines, making them ripe for real-time review (winbuzzer.com). Rare disease trials might particularly benefit from AI (to maximize scarce patient data) but pose challenges in data heterogeneity.

In response, one might argue for a **phased approach**: start with high-yield settings (e.g. solid tumors with imaging endpoints, or gene therapy first-in-human) and later extend. Provide evidence: e.g. oncology has historically low R&D efficiency, so speed benefits yield high drug development gains (as Makary noted, removing delays could especially accelerate cancer therapy approvals (www.axios.com)). If focusing on one disease group, cite prevalence or pipeline statistics to justify prioritization.

- **AI Use Cases Prioritization**: The RFI asks if priority should be given to particular AI applications (e.g. patient recruitment, safety monitoring) (regulations.justia.com). In practice, pilots may need to scope narrowly (a Full swath of technology is too broad for one pilot). Organizations should clarify their strengths. For instance, a tech vendor might propose focusing on AI-driven image analysis for response assessment, whereas a sponsor might emphasize recruiting and retention algorithms. Ideally, responses will explain how each use case would tangibly improve trial metrics.

For example, if suggesting emphasis on **safety monitoring**, cite data: in FDA's pilot, having review teams see real-time AEs allows immediate action (as opposed to meeting after a month's data lock (winbuzzer.com)). If recommending **recruitment AI**, one could cite evidence (like TrialGPT (www.fiercebiotech.com)) to show how dropout or delay rates fall.

- **Trial Size and Complexity**: Early-phase trials come in many sizes. Smaller first-in-human healthy volunteer studies might have simpler data streams, whereas multi-site phase I oncology studies generate large, complex data (imaging, labs). Respondents should consider a mixture: pilots could include both single-site and multi-site designs. Multi-site pilots stress-test data integration, whereas single-site pilots might allow deeper monitoring.

- **Endpoint Types**: Different endpoints suit the pilot differently. Real-time digital endpoints (e.g. continuous glucose monitoring, wearable sensor data) are immediately amenable to streaming, whereas traditional lab endpoints (blood tests done every visit) have lag by nature. Sponsors using continuous data streams might volunteer for early pilots. FDA's RFI would welcome ideas on specific endpoints to trial. For example, proposing inclusion of trials that use mobile health devices could allow very high-frequency monitoring inputs.

In summary, comments under Scope should identify the trial settings where AI-enabled acceleration is most needed and feasible. Organizations should leverage internal data or literature to make their case. For instance, *"Oncology trials with narrow patient populations and well-characterized biomarker readouts (like the Phase 2 TRAVERSE trial) are well suited because live data signals can be reviewed as they accrue (winbuzzer.com)."* An example company response: "We propose focusing on oncology and rare genetic diseases due to their mature biomarker strategies and small patient pools, which would disproportionately accelerate development for high-need areas."

2. Participant Selection and Diversity

Next, the RFI asks how FDA should select **participants** (meaning sponsors, trial sites, or technology providers) for the pilot (regulations.justia.com). FDA emphasizes wanting representation across *organization size (big pharma vs small biotech), capabilities,* and therapeutic areas. Key considerations include:

- **Sponsors and CROs**: FDA may select a small number of willing sponsor organizations (drug companies or academic consortia) to run proof-of-concept trials under the pilot. Comments should address what criteria justify selection. Potential criteria: past experience with advanced trial designs, data-sharing infrastructure, commitment to innovation, and track record on data integrity. For example, sponsors with existing electronic data capture and digital biomarkers would be ready to integrate real-time streams. On the other hand, involving smaller biotech firms (who typically lack massive infrastructure) would test the pilot's accessibility. Responders could propose a **tiered approach**: include at least one large pharma and one smaller entity, to compare implementation challenges and generalizability.
- **Site and Investigator Selection**: At the site level, pilots might require specialized capabilities (e.g. advanced hospital EHR systems, experience with digital endpoints). Responses may advise selecting sites (like large academic medical centers) with robust IT systems for initial pilots, while planning eventual extension to community sites. For example, industry partners have placed the TRAVERSE data feed "inside MD Anderson and Penn, two academic centers with established trial-data infrastructure" to reduce risk (winbuzzer.com). Proposals could detail how to ensure geographic and patient diversity (e.g. adding a mix of urban and rural sites or sites in underrepresented regions) to test system performance under varied conditions.
- **Technology Vendors**: The pilot necessarily involves third-party AI/data vendors (like Paradigm Health in the proof-of-concept). FDA seeks advice on selecting such partners. Criteria might include technology readiness level (TRL), compliance with data standards, cybersecurity track record, and transparency. Respondents should suggest mechanisms: for instance, requiring a prequalification of AI vendors, or

creating a forum (vendor agnostic) where multiple companies can propose solutions. Collaboration with academic data science groups is another model. The RFI also asks how to ensure participant representation across organization size and capability (regulations.justia.com); respondents might suggest an open call for proposals to draw in a range of entities, or partnering with consortia (e.g. TransCelerate) for reach.

- **Patient Group Input**: Intrinsically, while patients do not "run" these pilots, their groups are acknowledged stakeholders. The RFI inquires specifically about patient/investigator roles in AI governance (regulations.justia.com). Responses should note that patient advocates can advise on acceptable risk levels, interpretation of benefit, and data privacy concerns. For example, patients may demand strong privacy for their continuously streamed data or insist on transparent communication of AI's role in decisions. One strategy is to involve patient advocacy organizations early, perhaps as advisory members of pilot steering committees. We recommend distinguishing patient involvement both as subjects and as stakeholders who can provide input on trial desirability and communication.

In sum, comments on participant selection should articulate clear, justifiable criteria for *who* gets included in the pilot. Actual proposals could take the form: "We recommend selecting X sponsors (pharma Y and biotech Z) who have demonstrated digital trial capabilities, including Y's adaptive platform and Z's prior AI projects. FDA should also engage third-party tech vendors (like AI analytics firms) through a pre-competitive consortium. Sites should include at least one large academic health system and one community network to test different infrastructures." Backing up suggestions with examples (e.g. citing how Paradigm enabled the AstraZeneca and Amgen pilot data feeds (winbuzzer.com)) will strengthen the letter.

3. Collaboration Models and Partnerships

Effective collaboration is crucial for this project's success. The RFI asks about what partnership structures would be most effective (regulations.justia.com). Possible models include:

- **Sponsor–FDA Direct Collaboration**: A traditional model where each sponsor works directly with FDA. This may allow more control but can silo knowledge. The current proof-of-concept examples followed this path (AstraZeneca-FDA, Amgen-FDA) (content.govdelivery.com).
- **Public-Private Consortia**: A multi-stakeholder consortium (including multiple pharma companies, tech vendors, academic partners, and FDA) could be formed, akin to initiatives like the TransCelerate consortium for data sharing. This could facilitate pooling of expertise and dataset sharing, especially for cross-validation of AI tools. For example, if multiple sponsors pipeline to one platform, they could anonymize and share signals in a precompetitive manner, accelerating learning. Respondents might propose that FDA host regular consortium meetings or "hackathon" workshops to foster joint solution development, reducing duplication of effort.
- **Academic Partnerships**: Engaging academic research institutions can bring methodological rigor and independent evaluation. Tools developed in academia (e.g. open-source AI methods) could be tested in pilot trials. Academia can also analyze pilot results impartially. For instance, academic centers can contribute expertise in statistics and data science to validate AI outputs. The TRAVERSE pilot already involved MD Anderson and Penn as sites (winbuzzer.com), an example of integrating academia.

- **Patient-Focused Coalitions**: Though less common in operations, patient advocacy groups and ethicists can form a guiding coalition. Their role would be advising on trust issues, diversity, and ethical oversight. For example, participants might suggest forming a patient advisory board for the pilot, akin to patient groups that serve on trial steering committees.
- **Knowledge Sharing Mechanisms**: The RFI explicitly asks how FDA can facilitate pre-competitive knowledge sharing (regulations.justia.com). Stakeholders should propose concrete methods: e.g., a public repository of non-confidential trial milestones (while preserving CIP), regular webinars to share non-sensitive results, or FDA "challenge grants" awarding funding to analyze pilot data. The answer could note that the FDA intends to publish non-confidential learnings (as they did for MIDD pilots (regulations.justia.com)) and that respondents could support this with open-access publications or collaborative workshops.

Partnership proposals should emphasize common standards and governance. For instance, multiple vendors might agree on a common data format or API for trial signals, reducing integration costs. Similarly, sponsors could commit to shared lexicons for endpoints. A suggested rubric: "All pilot participants commit to an open data schema and reporting format; FDA can provide a standard template to streamline this process." This would answer the RFI's call for ideas on infrastructure and knowledge-sharing mechanisms (regulations.justia.com).

4. Operational Structure and FDA Support

The RFI solicits suggestions on what support FDA should provide to pilot participants and what infrastructure is needed (regulations.justia.com). Key points include:

- **Regulatory Engagement**: Participants likely need guidance on how the accelerated process fits into FDA's regulatory framework. For example, will these pilots be conducted under special INDs or safety protocols? Respondents might request FDA to offer an expedited interaction channel (e.g. dedicated pilot coordinators or "AI Navigators") to answer questions. For instance, if a sponsor's AI flagged a safety signal, what is the process for immediate reporting vs. traditional periodic safety update? Clarity on such "what if" workflows is needed. Sponsors may also need clarity on how this pilot will relate to existing regulations (e.g. ICH E8 guidance on trial design).
- **Technical Infrastructure**: The pilots require robust IT. FDA might provide (or endorse) cloud resources or data repositories. Responders could suggest that FDA establish a secure cloud environment or certify existing platforms. Press reports describe the pilots as using data streams through Paradigm Health; the privacy and security arrangements are not publicly detailed (winbuzzer.com); similar arrangements may be required. FDA may also need to expand bandwidth and analytics capacity to handle real-time feeds. Respondents should mention standards: e.g. use of HL7/FHIR for EHR data, CDISC SDTM for clinical data sets, or APIs for real-time communication.
- **Data Management and Confidentiality**: Infrastructure must balance data access with security. Likely needs include firewalls, role-based access, and audit trails. FDA's experience with other data initiatives (e.g. Sentinel database) could inform this. Comments could propose data governance boards and encryption standards.

- **Training and Change Management**: Both FDA staff and trial teams will require training. Respondents might recommend joint training sessions on data visualization tools, AI interpretation, and new standard operating procedures (SOPs). For example, one could propose that FDA offer workshops on interpreting AI model outputs, ensuring reviewers trust but verify AI signals.
- **Accommodating Varied AI Maturity**: Participants will have varying experience with AI. Some companies may already use sophisticated analytics; others may be exploring. The RFI asks how to accommodate "varying levels of AI maturity" (regulations.justia.com). It may be prudent to group participants by maturity level (e.g., bracketed cohorts where the first cohort has advanced use-cases, and a second cohort includes less-developed solutions). Alternatively, participants could be required to partner (e.g. a small biotech teams up with an AI vendor) so everyone has necessary expertise. Comments can recommend contingencies for both extremes.

Overall, the operational design should minimize new burdens on trial staff while maximizing consistency. For instance, if investigators must enter data into a new AI interface on top of their usual tasks, that might slow them down. Instead, one could suggest *passive* data collection (e.g. direct EHR integration, wearable devices) where possible. FDA guidance may need to clarify expectations: "In this pilot, sponsor must ensure their data pipeline meets X fidelity and resolution, but FDA will waive typical submission intervals for this trial due to the continuous review process." Arguments about the resource trade-offs (e.g. extra IT vs. time saved) should be grounded in evidence or analogies.

Metrics, Evaluation, and Evidence-Based Assessment

As outlined above, a central feature of the RFI is the focus on **metrics and success criteria** for the pilot. We examine each proposed evaluation area, suggest possible metrics (some quantitative, some qualitative), and cite evidence or analogs where available.

Trial Efficiency and Speed

The FDA wants to quantify *speed gains*. Key metrics could include:

- **Timeline Reductions**: The simplest measure is comparing time intervals before vs. after pilot. For example, measure the time from IND submission to trial completion, etc. Metrics might be: % reduction in *time to site activation*, *first subject first visit*, *last subject last visit*, and the gap between end of Phase 1 and start of Phase 2 (regulations.justia.com). Also, *time per patient accrual*. Using pilot versus historical or control arms, one could compute days saved or enrollment rate increase (patients per month).
- **Cycle Time for Decisions**: Since one goal is to enable faster decisions, measure how quickly go/no-go endpoints are reached. For example, if normally dose escalation decisions take X days after cohort completion, evaluate how much faster they occur with AI (perhaps in real time). Measure the lag between signal detection and regulatory action (e.g. issuing a study note).

- **Enrollment and Retention Efficiency**: If AI assisted recruitment, metrics include accrual rate (patients/week) and screen fail rate improvements. For retention, one could track whether dropout rates fell due to AI-driven engagement efforts (though this may be more PD for later phases). The RFI explicitly mentions quantifying recruitment and retention improvements (regulations.justia.com).

In terms of evidence, respondents might cite administrative delay in the path from a Phase 1 trial to an FDA application (www.axios.com). If the pilot achieves even half of Walsh's 20–40% reduction target, that would be a metric (e.g. "we observed a 25% faster trial completion"). It will be important to define baseline properly (likely historical/parallel trials).

Decision Quality

This addresses the *accuracy and timeliness* of key decisions:

- **Go/No-Go Concordance**: How often do AI-supported decisions agree with independent expert judgments or final outcomes? One can compare decisions made with AI assistance to those from retrospective review without AI. For example, if an AI model predicts "not progressing" and the study was indeed halted, that's concordant. FDA asks about metrics for concordance (regulations.justia.com). A high concordance ratio (e.g. >90%) would indicate robust decision support.
- **Reduction in Late Failures**: FDA suggests measuring if improved early decisions lead to fewer Phase 3 failures (regulations.justia.com). While meaningful, this is long-term; for pilot purposes one could use proxy outcomes. For example, measure if the predictive models used reduce the projected risk of later-phase failure (via simulation). Historical data might show X% of Phase 1 drugs fail in Phase 3; if AI-based stopping would have avoided 50% of those, that's a metric.
- **Safety Decision Impact**: More timely AE signals (see below) could be considered a decision quality measure: e.g. how much sooner was an FDA safety recommendation issued?

Again, evidence from other domains can be cited. For instance, in diagnostic AI studies, concordance metrics (sensitivity/specificity) are common. The pilot could similarly track how often AI "would have" correctly indicated outcomes.

Participant Safety and Data Integrity

FDA is concerned that AI use does not compromise safety monitoring. Metrics here might include:

- **Signal Detection Time**: Compare time from actual event occurrence to detection/flagging by system. The earlier this is, the better. For instance, measure the number of days saved in flagging a safety signal versus the conventional process.
- **Adverse Event (AE) Metrics**: Compare rates of protocol deviations or serious adverse events captured per month. Ideally, AI should reduce missed events. Also track if any AEs occur that were not predicted.
- **Data Completeness/Accuracy**: AI may improve data flow, but could risk gaps if feeds fail. Metrics could include percentage of expected data points successfully received and validated. Any system downtime or data loss events should be recorded.

In responses, stakeholders should outline how they would ensure data fidelity (e.g. end-to-end encryption checks) and how to measure it (e.g. error rates, missing data percentage). References may come from data science literature on streaming data quality.

AI System Performance

This category involves classical ML metrics applied to the models used:

- **Accuracy and Robustness**: For any predictive model, measure accuracy (e.g. AUC-ROC for classification tasks) on hold-out validation sets. If an AI is used for a go/no-go prediction, what fraction of predictions are correct? Also track *model drift*: does performance degrade as the trial population shifts? For robustness, perhaps simulate noise injection or test on subgroups.
- **Generalization Across Sites**: FDA asks how to measure performance across populations or sites (regulations.justia.com). This could be quantified by training on part of data and testing on another (cross-site validation). Performance variance by therapy area or demographic should be assessed.
- **Explainability**: While not quantitative, it overlaps here: e.g. percentage of predictions accompanied by an understandable explanation (via SHAP values, decision trees, etc.).

Since AI models in clinical trials are relatively new, there is little “off-the-shelf” experience. However, analogies from medical device AI can be drawn. For example, the FDA’s guidance on AI mentions reporting validation results and limits of use. Sponsors might cite those expectations as benchmarks for the pilot (e.g. achieving >95% sensitivity in detecting safety signals).

Trustworthiness and Fairness

Aligned with NIST RMF, this area is more qualitative but still has metrics:

- **Validation Evidence**: Demonstrating model **validity** in clinical context. This could include retrospective validation on historical trial datasets, clinical expert review of model outputs, and sets of test cases. A robust validation protocol (e.g. k-fold cross-validation, independent test sets) should be documented.
- **Safety/Risk Mitigation**: Metrics here might be checklists (yes/no) for implemented governance controls: for example, having a “human-in-loop” check for any AI-suggested decision, or a monitoring team reviewing flagged signals. If implemented, the absence of adverse events due to AI errors could be a (blunt) outcome metric.
- **Explainability Metrics**: Some research defines explainability quantitatively (e.g. fidelity of simplified explanations, or number of features used in a rule-based surrogate). Stakeholders can propose using such metrics if explainable AI techniques are applied. Otherwise, they should outline how they will ensure transparency (e.g. maintaining logs of model decisions, code reviews).
- **Fairness Metrics**: A major concern is that AI might perform unevenly across subgroups. FDA asks how to assess fairness across demographic and clinical groups (regulations.justia.com). Common fairness metrics (disparate impact ratio, equalized odds) could be used. For example, measure whether the AI

model's false positive/negative rates are similar across age, sex, or race groups in the trial data. Any disparities should be minimized.

Given FDA's caution on bias (noted in literature: "algorithms trained on historical data often inherit biases" (pmc.ncbi.nlm.nih.gov)), it would be prudent for responses to spell out plans to evaluate subgroup performance.

Comparative Evaluation

The RFI invites comments on how to compare pilot outcomes to a baseline (FDA labels this "Comparative Evaluation" (regulations.justia.com)). Options include:

- **Concurrent Controls**: Run a parallel non-AI arm (or concurrent non-AI regions) and compare outcomes. In practice, this could mean comparing the real-time trial to a matched study with traditional data flow, if available.
- **Historical Controls**: Compare metrics from the pilot against past trials' results (time to complete, safety outcomes). This is easiest but differences in protocol could confound.
- **Simulation Studies**: Especially if real controls are infeasible, use statistical simulation to project what the trial timeline would have been under normal procedures. For instance, one might simulate expected delays using historical data.

Respondents should recommend a strategy and justify it. For example: "We propose using historical data from similar phase 1 trials as a control, adjusting for confounders. We will use statistical matching or propensity scoring to account for differences in design. Alternatively, if multiple similar trials run in parallel, we could run one with AI and one without to get a direct comparison."

Qualitative Outcomes

Finally, FDA calls for evaluating intangible factors (trust, usability, scalability) (regulations.justia.com). These can be measured by:

- **Stakeholder Surveys**: Collect structured feedback from investigators, monitors, and patients on their trust in the AI systems and their perceived utility. For example, a Likert-scale survey on "ease of use of the new system" or "confidence in AI-generated alerts."
- **Documentation of Workflow Changes**: Track how study workflows evolved. Did site staff report spending less time on forms? Did FDA reviewers reduce paper handling? These qualitative reports, though anecdotal, can be systematically gathered via interviews or questionnaires.
- **Generalizability Assessment**: Consider how easily the pilot approaches could be scaled. For example, how many sites would have to upgrade their systems, or what training investment is needed? One might measure "time required to onboard a new trial site into the system" as a proxy.

- **Adoption and Continuation**: A long-term metric is whether sponsors/investigators choose to continue using the system beyond the pilot. Though outside the initial evaluation window, early signs (e.g. sponsor intent to use real-time monitoring in their next trial) could be probed via follow-up.

The RFI specifically mentions measuring "perceived value, scalability, and operational feasibility" (regulations.justia.com). Survey data or structured interviews can capture perceptions of value (e.g. "Using this system was worth the effort"), while tracking staff hours or costs can measure feasibility.

In writing these sections, it would be beneficial to cite analogous evaluation efforts. For instance, respondents could propose assessing time investment per site as a function of the new system deployment.

Considerations of Trust, Ethics, and Equity

Integrating AI into clinical trials raises broader issues beyond technical metrics. We briefly highlight some key themes the FDA and respondents should consider:

- **Bias and Fairness**: As noted, AI models can propagate historical biases (pmc.ncbi.nlm.nih.gov). In clinical trials, this could manifest if, for instance, models predict poor outcomes for an underrepresented group simply because few such patients were in training data. Commenters should discuss strategies to prevent this (e.g. oversampling minority data, fairness-constrained learning) and how to monitor it (the fairness metrics above).
- **Explainability and Accountability**: Regulators must be able to audit AI decisions. The NIST RMF principal of *explainability* implies having traceable reasoning. Sponsors might propose that any AI recommendation come with supporting evidence (e.g. "AI logic shows toxicity high at predicted probability X"; or adversarial testing). Accountability also means knowing who is responsible if the AI advice is wrong. The response guide should underline that ultimate liability remains with investigators and sponsors, even if aided by AI.
- **Privacy and Data Sharing**: Real-time trials will often involve sensitive health data (e.g. genomics, unblinded safety data). Ensuring HIPAA compliance and data security is non-negotiable. Indeed, the FDA RFI explicitly includes privacy protections as part of trust (regulations.justia.com). Responders should detail encryption, access controls, and de-identification processes. For example, respondents could describe how patient data would be de-identified before streaming (winbuzzer.com). Going further, health data anonymization techniques (like differential privacy) might be employed.
- **Patient Perspectives**: Real-time data collection might require patient consent to new data uses. For instance, streaming continuous glucose monitor data to regulators is novel. Responders should consider how to inform and protect trial participants: Will patients consent to share such granular data? Could participants opt out of certain analyses? These questions should be discussed, perhaps recommending IRB and informed consent updates.
- **Global Harmonization**: If successful, this pilot may set precedents internationally. Respondents (especially large sponsors) might mention how pilot outcomes could align with European regulators (the EU AI Act is already in force and applies in phases). For now, emphasizing interoperability with

standards used elsewhere (e.g. HL7/FHIR) could help global use.

Including these qualitative considerations shows awareness of the *trust* dimension of FDA's inquiry (regulations.justia.com). While not all questions require empirical answers, citing existing ethical frameworks (for example, published peer-reviewed literature on AI ethics) and aligning with NIST principles will demonstrate thoroughness.

Data Analysis and Evidence-Based Arguments

To make persuasive comments, respondents must ground points in data and references. Here we highlight some relevant studies and data that can bolster arguments:

- **Drug Development Efficiency**: The ACS report updated success rates of clinical trials (13.8% from Phase 1) (cen.acs.org), indicating room for improvement. This can support the need for innovation: "Even modest gains (e.g. raising Phase 1 success by a few percent) represent substantial public health benefits." Additionally, Makary's remark that 45% of the Phase 1-to-NDA timeline is paperwork (www.axios.com) quantifies the potential time-saving impact; one could argue that reducing just half of that "dead time" with AI yields a major speed-up.
- **Cost Savings and Return on Investment**: The winbuzzer piece projects $120M/year saved (winbuzzer.com). If one extrapolates, even if the pilot costs $X million, the net savings in time and manpower (3,000 staff equivalents (winbuzzer.com)) justifies the effort. These figures could be cited to argue that FDA modernization is economically rational.
- **AI Performance in Healthcare**: Beyond trial recruitment (www.fiercebiotech.com), other evidence abounds. Respondents who draw on evidence from other fields should support each claim with peer-reviewed sources.
- **Existing Regulatory Inputs**: While not data per se, FDA guidance and white papers can be marshaled as evidence. For example, referencing the FDA's public recognition of these challenges (the same RFI summary is itself a source (regulations.justia.com)). The April 30, 2026 HHS press release compiles reactions from many stakeholders, including an Amgen executive who said the program "has the potential to be transformational on so many levels in how we do clinical research" (www.hhs.gov). For instance, STAT News quoted MD Anderson's Jennifer Litton observing that current multi-system data delays take "time away from patients" (www.hhs.gov); quoting such sentiment shows clinical urgency.
- **Governance Frameworks**: The NIH and NIST outputs can be cited for best practices. If respondents propose a trust model, they could cite the NIST AI RMF text or use terms from relevant standards (e.g. ISO standards on AI ethics).
- **Case Numbers and Technical Metrics**: If organizations have proprietary pilot data or simulations (even small-scale), they should share summary results. For example, a CRO might present that its AI scheduling tool reduced site follow-ups by X%. Or a tech vendor might show accuracy figures from their

algorithm. These real numbers, though likely confidential, could be described qualitatively if not publicly citable.

Overall, responses should rely on a mix of literature (peer-reviewed wherever possible) and concrete examples. The citations in this report (e.g. (www.fiercebiotech.com) (winbuzzer.com)) illustrate the depth of sourcing expected. Stakeholders may also cite:

- FDA regulatory precedents (e.g. previous pilot announcements (regulations.justia.com)).
- Industry white papers (with caution, ensure credibility).
- Academic studies on AI in trials or drug development (as references).

Discussion of Implications and Future Directions

Looking beyond the immediate pilot, implementing AI in early-phase trials has far-reaching implications:

- **Accelerated Access to Therapies**: If successful, real-time AI review could shorten trial phases and reduce attrition, meaning patients gain access to new treatments faster. As Dr. Paul Burton (Amgen Senior Vice President and Chief Medical Officer) said, this could be “transformational on so many levels in how we do clinical research” (www.hhs.gov). Over time, one could envision trials becoming *continuous processes* rather than discrete experiments. For example, instead of stopping a trial mid-phase to file for permission to start Phase 2, evidence streams could seamlessly support extension.
- **Data Ecosystem Evolution**: A shift to AI-driven trials would likely spur investments in health data infrastructure: interoperable EHRs, cloud platforms, and data standards. In the FDA pilot, the Paradigm platform acts as a central hub (winbuzzer.com), but scale-up might require interoperable networks among hospital systems and sponsors. Industry may move toward common data models (e.g. GA4GH, OMOP) to facilitate interchange.
- **Regulatory Processes**: The FDA is currently piloting, but if this model proves effective, it could influence future regulatory frameworks. For instance, the concept might spread to later-phase trials or post-market studies. It might also lead to guidance documents on best practices for AI in trials. FDA could build on its draft guidance on the use of AI to support regulatory decision-making for drugs and biological products (FDA guidance page). Organizations could suggest ideas like formalizing “Data Abstraction Standards” or “Real-Time Trial Reporting Rules” post-pilot.
- **Culture and Workforce**: The need for data scientists within regulatory and sponsor teams may grow. The budget savings Makary cited (winbuzzer.com) hinted at re-hiring 3,000 scientists; presumably, these roles will focus on data review and analysis rather than manual paperwork. Stakeholders should anticipate training needs for clinicians and statisticians to work with AI tools.
- **Ethical and Trust Evolution**: Continuous trials raise ethical questions (e.g. about patient autonomy if data always flows to authorities) and trust in regulators. Public understanding campaigns may become important. Patient roles could evolve: those in real-time trials may need extra counseling on data use.

The RFI signals a collaborative approach to these issues, but they will remain critical long-term.

- **Global Leadership and Competition**: The FDA frames this as maintaining U.S. leadership in biomedical innovation (www.axios.com). Reports note interest globally (e.g. in China, leading to concerns U.S. must move quickly (www.axios.com)). Thus, a successful pilot could set an international precedent. However, if U.S. industry responds poorly (e.g. through slow adoption), other jurisdictions may forge ahead.

Overall, the implications are profound: from this pilot we may see a step change in how both trials and regulation are conducted. In this context, it is wise for respondents to articulate not just immediate concerns but also envision longer-term integration. For instance, one could write: “This pilot lays groundwork for a future where clinical trials become dynamic data ecosystems. We recommend that findings be published and integrated into regulatory frameworks for Phase 2 and post-market studies, expanding FDA’s continuous review paradigm.”

Conclusion

The FDA’s RFI on AI-enabled early-phase clinical trials represents a watershed moment for drug development. Through extensive stakeholder input, the agency seeks to chart a path for harnessing cutting-edge AI and data science in a way that maintains patient safety and scientific integrity. This response guide has dissected the RFI’s content and provided analysis across all aspects of the pilot design: from trial use cases and participant selection, to collaboration models and evaluation metrics, to trust and ethics.

Key takeaways include the enormous potential benefits of real-time data (including an FDA official’s projection that real-time review could shave 20–40% off overall trial time—an aspirational estimate, not a pilot result (winbuzzer.com) (www.axios.com)) and the necessity of rigorous safeguards (aligned with NIST RMF (regulations.justia.com) (pmc.ncbi.nlm.nih.gov)). The FDA has outlined clear questions, and responders should structure comments to systematically address these with evidence-based arguments. Using specific data and studies—such as those cited here—will strengthen any submission.

As this guide emphasizes, any response should not only list ideas but support them with citations, case examples, and logical analysis. For instance, recommending a particular AI metric should cite how it’s used in analogous settings; suggesting a collaborative model should point to successful examples (like the Paradigm Health partnership (winbuzzer.com) or TransCelerate processes). Clarity and specificity will be crucial, as regulators seek actionable suggestions.

Finally, stakeholders should remember this RFI is just the start. The application of AI in clinical trials is rapidly evolving; by contributing thoughtfully now, respondents help shape FDA policy and the future of medicine. Success in the pilot could herald a new era—**“real-time, continuous trials”**—where promising therapies reach patients faster, and clinical research operates at the cutting edge of technology (www.hhs.gov) (www.axios.com).

We trust that this report will serve as a valuable resource for anyone preparing comments on the FDA’s AI early-phase trials RFI.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.federalregister.gov/documents/2026/05/28/2026-10602/ai-enabled-optimization-of-early-phase-clinical-trials-pilot-program-request-for-information
2. https://regulations.justia.com/regulations/fedreg/2026/04/29/2026-08281.html
3. https://advocacy.sba.gov/2026/04/30/fda-requests-information-on-ai-enabled-optimization-of-early-phase-clinical-trials-pilot-program
4. https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn
5. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological
6. https://cen.acs.org/articles/96/i7/Drug-development-success-rates-higher.html%3B
7. https://www.axios.com/2026/04/29/fda-ai-track-clinical-trials-real-time
8. https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials
9. https://www.fiercebiotech.com/cro/ai-model-matches-patients-clinical-trials-fast-human-only-slight-dip-accuracy
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12. https://www.govinfo.gov/content/pkg/FR-2026-04-29/html/2026-08281.htm
13. https://pmc.ncbi.nlm.nih.gov/articles/PMC12888102
14. https://www.hhs.gov/press-room/wtas-fda-announces-major-steps-implement-real-time-clinical-trials.html
15. https://legiseye.com/en/law/usa/0a731933
16. https://regulations.justia.com/regulations/fedreg/2018/04/17/2018-08010.html
17. https://arxiv.org/abs/2510.06567

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