FDA Real-Time AI Clinical Trials: AZ & Amgen Pilot

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Executive Summary

The U.S. Food and Drug Administration (FDA) has initiated a groundbreaking **real-time AI-enabled clinical trial pilot** aimed at dramatically accelerating drug development ([1] www.fda.gov) ([2] www.axios.com). On May 19, 2026, the FDA named **AstraZeneca and Amgen** as the first sponsors in this pilot, involving live, cloud-based monitoring of two oncology trials (AZ's Phase 2 *TRAVERSE* trial in mantle cell lymphoma; Amgen's Phase 1b *STREAM-SCLC* trial in small cell lung cancer) ([3] www.fda.gov) ([4] pharmaphorum.com). Under this model, de-identified safety and efficacy signals (not full raw datasets) are streamed continuously to FDA reviewers and sponsors via a cloud platform (provided by Paradigm Health) ([5] winbuzzer.com) ([6] www.clinicalresearchnewsonline.com). Early estimates suggest **20–40% reductions in trial duration** compared to conventional methods ([7] winbuzzer.com) ([2] www.axios.com), translating to multi-month or multi-year time savings. The FDA projects this could free ~$120 million annually (enabling rehiring of ~3,000 scientists) from efficiencies gained ([7] winbuzzer.com).

Alongside the trial launches, FDA issued a **Request for Information (RFI)** on "AI-enabled optimization of early-phase clinical trials," soliciting industry input on pilot design, metrics, and governance ([1] www.fda.gov) ([8] winbuzzer.com). The RFI is open for comments through **May 29, 2026**, with final selection criteria to be published in July and additional pilot participants chosen by August ([9] www.fda.gov) ([10] winbuzzer.com). This compressed timeline – driven by public feedback – contrasts sharply with typical multi-year rulemakings and underscores the FDA's urgency to operationalize real-time approaches ([10] winbuzzer.com).

This report provides a comprehensive analysis of the FDA's Real-Time AI Clinical Trial Pilot. We examine the **historical context** and motivations for faster trials, the **technical architecture** (cloud data pipelines, AI analytics, and regulatory dashboards), and the **operational playbook** for cloud-based monitoring. Using the AZ and Amgen trials as case studies, we detail how data flows will change and how stakeholders must adapt workflows. We present **data-driven estimates** of efficiency gains, discuss potential cost impacts, and consider expert perspectives – from agency leaders and bioethicists to industry analysts – on benefits and risks ([11] www.fiercebiotech.com) ([12] aesopacademy.org). We also review relevant policies (e.g. recent FDA guidances on remote data capture ([13] collections.nlm.nih.gov) and AI risk management ([14] www.clinicalresearchnewsonline.com)) that form the regulatory backdrop. Finally, we outline challenges (data privacy, analytical validity, equity of access) and future directions if such models are scaled beyond these initial trials. All claims and projections are supported by the latest FDA announcements and independent analyses ([7] winbuzzer.com) ([6] www.clinicalresearchnewsonline.com).

Introduction

Clinical trials have long been bottlenecks in bringing new therapies to patients. Historically, it often takes **10–12 years** for a promising drug to gain FDA approval ([2] www.axios.com). FDA Commissioner Marty Makary has observed that *"45 percent of the time is dead time"* in trials, spent on administrative tasks and waiting for locked datasets ([11] www.fiercebiotech.com). In the traditional model, investigators collect data (e.g. lab results, adverse events) at sites, which sponsors compile and submit only after periodic data locks. Reviewers then study these static reports, meaning the FDA may not see critical safety or efficacy signals until months or years after they occur.

The **FDA's new Real-Time AI Clinical Trial Pilot** is designed to invert this process. Instead of waiting for final submissions, FDA reviewers will have a live view of trial data as it accrues in the cloud ([5] winbuzzer.com) ([6] www.clinicalresearchnewsonline.com). Makary describes this as a fundamental transformation: *"FDA regulators will view safety signals and clinical endpoints in the cloud in real time as they are occurring"* ([15] www.fiercebiotech.com). The aim is to eliminate "dead time" by enabling continuous monitoring and faster decision-making without compromising trial integrity. This aligns with FDA's longer-term goal of "real-time, continuous trials across all phases of drug development" ([16] www.fda.gov) ([17] pharmaphorum.com).

Technological advances have made this possible. Electronic health record (EHR) systems, cloud computing, and modern AI tools can extract structured data from routine care and trial visits. Indeed, FDA's December 2023 guidance on digital health technologies states that *"computing platforms, connectivity, software, and/or sensors"* (so-called Digital Health Technologies, DHTs) can facilitate remote data capture, provided they are validated and *"fit-for-purpose"* ([13] collections.nlm.nih.gov).The new pilot leverages these capabilities: Paradigm Health's platform, for example, pulls patient data directly from EHRs and algorithms to identify prespecified endpoints in real time ([18] www.clinicalresearchnewsonline.com) ([6] www.clinicalresearchnewsonline.com). On the regulatory side, FDA has shown growing embrace of innovative approaches. In early 2026 it announced that one well-controlled trial plus confirmative evidence (rather than the old two-trial standard) can support approvals, reflecting a willingness to use diverse data sources in decision-making ([19] winbuzzer.com). Furthermore, FDA's Chief AI Officer reports that over 80% of FDA staff now use generative AI tools in their work (up from ~1% in early 2025) ([20] winbuzzer.com), indicating the agency's readiness to blend AI into regulatory review.

International pressures also motivate change. Agency leaders note the need to keep U.S. biopharma competitive with countries like China ([2] www.axios.com) ([21] www.hoganlovells.com). The COVID pandemic demonstrated the value of rapid data analysis, further pushing regulators to modernize. In this context, the Real-Time AI pilot represents a **major step** in FDA's modernization roadmap ([1] www.fda.gov) ([2] www.axios.com). It is preceded by other efforts (e.g. risk-based monitoring guidances and the Clinical Trials Transformation Initiative) but is unprecedented in having live AI-driven data review by regulators.

FDA Real-Time Clinical Trial Initiative

Proof-of-Concept Studies (AstraZeneca & Amgen)

On April 28, 2026 (effective May 19 press outreach), FDA announced **two proof-of-concept "real-time clinical trials"** ([1] www.fda.gov) involving AstraZeneca and Amgen. These trials will **stream data to FDA reviewers via the cloud** as the trials progress. Specifically:

- **AstraZeneca's TRAVERSE Trial:** A Phase 2 multisite study in treatment-naïve mantle cell lymphoma. It tests a combination therapy (the BTK inhibitor acalabrutinib/Calquence plus AbbVie/Roche's venetoclax (Venclexta) and rituximab) ([4] pharmaphorum.com). The trial is conducted at major centers including the University of Texas MD Anderson and the University of Pennsylvania ([4] pharmaphorum.com). FDA has already *"received and validated signals"* from TRAVERSE through Paradigm Health's system, demonstrating a working live feed ([22] www.fda.gov) ([23] pharmaphorum.com).
- **Amgen's STREAM-SCLC Trial:** A Phase 1b study in limited-stage small cell lung cancer. It evaluates Amgen's bispecific T-cell engager ("BiTE") agent Imdelltra (tarlatamab) targeting DLL3 ([24] pharmaphorum.com). Final site selection is underway, but the design will similarly stream key trial data to the FDA. (According to FDA, the STREAM trial is still adding sites.)

In both cases, **no changes are made to how patients are treated or how data are collected** – the difference is in *when and how* FDA sees the results. As FDA's press release emphasizes, only *"who sees the signals and when"* is new ([25] winbuzzer.com). Sites and sponsors continue standard operations, but safety, dosing, and biomarker signals (after appropriate de-identification) flow to a shared cloud environment. This allows real-time oversight: for example, if a subject in TRAVERSE spikes a fever or a tumor reduction is observed, FDA reviewers can see that **within days**, not months ([26] winbuzzer.com) ([27] www.fiercebiotech.com).

Technically, this is enabled by **Paradigm Health's Study Conduct platform**. Paradigm ingests EHR and other clinical data, applies algorithms defined by FDA (e.g. what constitutes a reportable adverse event or endpoint), and transmits *only the critical signals* to both the sponsor and the FDA ([18] www.clinicalresearchnewsonline.com) ([6] www.clinicalresearchnewsonline.com). Crucially, the data pathway is secure, traceable and auditable. Paradigm developed the framework in collaboration with FDA, ensuring interoperability and validation protocols ([28]

www.clinicalresearchnewsonline.com). Only fields relevant to prespecified safety or efficacy are shared in real time, protecting patient privacy and sponsor proprietary data. FDA's Chief AI Officer Jeremy Walsh contrasts this with older data practices: the agency is *not* asking for raw patient records, only curated signals ([29] www.clinicalresearchnewsonline.com).

From the outset, FDA leaders have touted the potential impact. In public statements, Makary and Walsh call the day *"milestone"* and challenge the notion that trials must take over a decade ([2] www.axios.com). Walsh estimates that the real-time approach could *"shave off"* up to 20–40% of total trial time ([2] www.axios.com), not by skipping safety steps, but by removing delays between phases. Jefferies analysts similarly note that continuous data flow lets the FDA make decisions faster *"all while preserving the foundational requirements of safety, monitoring, governance, and data integrity"* ([30] www.biospace.com).

Trial (Acronym)	Sponsor	Phase	Indication/Therapy	Cloud Platform	Sites (Examples)
TRAVERSE (AZ)	AstraZeneca	Phase 2	Mantle Cell Lymphoma (acalabrutinib + venetoclax + rituximab) ([4] pharmaphorum.com)	Paradigm Health Real-Time	UT MD Anderson; Univ. of Pennsylvania ([4] pharmaphorum.com)
STREAM-SCLC (Amgen)	Amgen	Phase 1b	Limited-stage Small Cell Lung Cancer (bispecific BiTE "Imdelltra"/tarlatamab) ([24] pharmaphorum.com)	Paradigm Health Real-Time	Pending final site selection ([24] pharmaphorum.com)

Table 1: Overview of the FDA's first two real-time clinical trials (as announced). Both use Paradigm Health's cloud platform to stream de-identified trial data to the FDA in real time ([18] www.clinicalresearchnewsonline.com) ([4] pharmaphorum.com).

FDA's official news release and related briefings emphasize that these trials have already proved that the concept works: the AZ trial data pipeline is live and stable, meaning the pilot starts with a *working* infrastructure rather than a theoretical model ([5] winbuzzer.com). This allows the agency to begin identifying any process issues immediately (e.g. if data feeds need adjustment) as it accepts live trial signals for the first time ([20] winbuzzer.com) ([5] winbuzzer.com).

RFI and Pilot Program Details

In conjunction with announcing the proof-of-concepts, FDA published a **Federal Register Request for Information (RFI)** titled *"AI-enabled optimization of early-phase clinical trials pilot program"* ([31] winbuzzer.com). This RFI invites sponsors, CROs, and investigators to comment on scaling up real-time, AI-driven monitoring beyond the initial oncology trials. It specifically seeks input on:

- **Study Selection**: FDA is interested in additional early-phase studies (oncology, neurology, rare diseases) where small populations and dense biomarkers make real-time monitoring most effective ([32] winbuzzer.com).
- **Data Architecture**: Comments on how to design data pipelines, including interoperability standards, validation checks, and audit trails, are requested. The RFI outlines expected requirements for data formats and security.
- **Governance & Workflow**: The agency asks respondents to propose how triggers, queries, and decision processes should work in continuous mode. For example, which interim signals would prompt FDA intervention, and how disagreements should be handled ([33] winbuzzer.com).
- **Success Metrics**: Feedback on what evaluation metrics to use (e.g. time savings, detection of safety signals, decision quality) is also solicited.

Notably, the RFI deadline is **May 29, 2026**, giving industry a few weeks to weigh in ([9] www.fda.gov) ([34] winbuzzer.com). The accelerated schedule reflects FDA's intent: *public comments until May 29; final selection criteria by July; pilot selections by August* ([10] winbuzzer.com). By streamlining decisions about additional participants into months rather than years, FDA ensures the pilot's expansion remains an operational process rather than drawn-out rulemaking.

The compressed timeline is unusual for FDA. Hogan Lovells notes that traditionally new trial paradigms could take years of guidance development, but under the RFI approach FDA can rapidly refine pilot design based on industry needs ([10] winbuzzer.com). By July 2026, sponsors who expressed interest and meet criteria will likely have to be ready to connect live data pipelines. The RFI thus catalyzes a near-term project: any sponsor with an ongoing Phase 1/2 Program could race to join the pilot, creating early "real-time" competition among drugs.

Reactions and *"Next Steps"*

Following the announcement, industry and analysts offered cautious optimism. Evercore ISI analysts in April called the initiative a *"logical next step"*: regulators *"responding to a fast-moving technology and beginning to define a workable pathway"* ([35] www.fiercebiotech.com). Similarly, Jefferies noted that this approach could *"compress drug development timelines"* for companies, enhancing peak sales potential ([30] www.biospace.com) ([36] www.biospace.com).

At a May 15 virtual industry information session, FDA officials answered questions on the RFI, reiterating that more early-phase trial changes are expected in the coming months and stressing that this pilot is part of a broader transformation of the drug review process ([21] www.hoganlovells.com) ([37] www.hoganlovells.com). Jeremy Walsh emphasized that real-time monitoring will *"initially run in parallel with traditional data submissions,"* preserving standard review milestones like pre-IND or end-of-phase meetings ([37] www.hoganlovells.com). The pilot is thus seen as a learning exercise: an opportunity to determine *how* to integrate continuous data oversight, rather than an immediate replacement of established regulatory processes ([37] www.hoganlovells.com).

In sum, the FDA's pilot program is formally underway. The next concrete milestones are the RFI comment period (closing 5/29), followed by RFI-driven guidance in July and new pilot enrollments by August. This unprecedented, near-real-time timeline underscores FDA's commitment to rapid innovation in trial oversight ([10] winbuzzer.com) ([9] www.fda.gov).

Technical Implementation

The FDA's real-time trial pilot relies on cutting-edge data infrastructure and AI tools to transfer and interpret trial data instantaneously. The core technical elements include:

Cloud Platforms and Data Flow

Data Sources and Integration. Patient data originate at trial sites (hospitals and clinics) through EHRs, lab systems, imaging systems, and other sources. Traditionally, sites enter such data into an electronic data capture (EDC) system, and only periodic exports (CRFs) are sent to the sponsor. Under the new model, data are streamed immediately. Paradigm Health's Study Conduct platform connects to site EHRs and the sponsor's EDC, continuously extracting relevant fields (e.g. vital signs, lab values, dosing records, imaging read-outs). According to Clinical Research News, *"Paradigm Health's platform is enabling real-time data review by the FDA"* by *"capturing data directly from electronic health records and other structured sources, algorithmically evaluating FDA-defined data points … and transmitting only the critical signals"* ([6] www.clinicalresearchnewsonline.com).

Shared Cloud Environment. Once extracted, data signals are uploaded to a secure, cloud-based repository accessible by both the sponsor and FDA. In practice, this means FDA reviewers log into a centralized dashboard where trial data appear live. Paradigm's solution validates each signal against agreed schemas to prevent errors. Importantly, only de-identified or coded data fields are shared, minimizing privacy risks. As FDA noted, *"the data transferred through the real-time platform is traceable, auditable, and protects patient privacy, while minimizing the transfer of patient data"* ([38] www.clinicalresearchnewsonline.com). Overhead is kept low by filtering out extraneous information; for example, only predefined biomarkers and critical safety endpoints are reported, not entire lab panels or free-text notes.

AI Processing and Alerts. The platform incorporates algorithmic checks for safety signals (e.g. unusually high lab values or clusters of adverse events) and efficacy endpoints. These may involve simple threshold alerts or more complex AI analyses. When a pattern of concern emerges (such as a potential toxicity trend), the system can flag it immediately on the FDA dashboard. While not fully elaborated publicly, FDA Chief AI Officer Jeremy Walsh has indicated that natural language and data mining tools (like FDA's internal "Elsa" system) may help reviewers interpret incoming streams. However, he stressed that this pilot's AI component focuses on *structured telemetry*, not on creative data imputation ([39] winbuzzer.com) ([37] www.hoganlovells.com). In sum, AI helps sift the data flow so FDA expertise is applied only where needed.

Regulatory Validation. Central to implementation is the establishment of criteria and validation protocols. Prior to data exchange, FDA and each sponsor negotiated which data fields and signal definitions would be used. Paradigm's engineers worked with FDA to specify the data architecture and ensure all transmitted signals meet regulator needs ([38] www.clinicalresearchnewsonline.com). Every transmitted value is double-checked: for example, if a site records a new symptom, the sponsor must confirm it matches the agreed format before it enters the FDA view. In effect, this maintains data quality: FDA is not blindly ingesting raw data, but receiving vetted signals. Similarly, the FDA's NIST-aligned risk framework guides this process: the RFI explicitly states that the pilot will follow the NIST AI Risk Management Framework for safety and trustworthiness ([14] www.clinicalresearchnewsonline.com). This means sponsors must demonstrate that their algorithms are reliable, and any software used (like Paradigm's) is qualified.

Cloud-Based Monitoring Architecture

The physical architecture can be summarized as follows:

1. **Site → Cloud:** Each trial site connects patient data systems (EHR, lab, imaging) to the cloud platform. This may use secure APIs or data intermediaries. Data flow is real-time or near-real-time (e.g. nightly batch runs).
2. **Sponsor → Cloud:** The sponsor's study management system (e.g. EDC, CTMS, IVRS) also feeds into the cloud, ensuring doses administered and queries are synchronized.
3. **Data Aggregation Layer:** Paradigm's software layer aggregates these inputs, de-identifies them, and stores them in a centralized database with strong encryption and audit trails ([28] www.clinicalresearchnewsonline.com).
4. **Analytics Engine:** On top of the database, automated scripts and machine-learning models evaluate each new record for predefined criteria (safety thresholds, response markers, etc.).
5. **User Interface:** FDA reviewers use web-based dashboards (with metadata tagging for each patient and data type) to monitor incoming signals. They can filter by subject or event type. Sponsors have a similar interface to review what FDA sees.
6. **Alerts & Communication:** If certain flags are hit (e.g. three patients have Grade 3 toxicity in a row), email/SMS alerts notify relevant teams. Protocols are in place for FDA to send queries through the sponsor's clinical operations group for clarification or action.

This architecture essentially **inverts the classic data flow**: instead of site → sponsor → FDA (with long delays), we have site → (cloud) → FDA & sponsor concurrently. Table 2 contrasts key aspects of these models:

Aspect	Traditional Model	Real-Time Cloud Model
Data Flow	Site → Sponsor EDC (periodic) → FDA (batch submit) ([40] www.fda.gov)	Site & Sponsor → Shared Cloud Repository (continuous) ([41] winbuzzer.com)
Monitoring Frequency	Periodic (e.g. monthly CRF reviews, DSMB meetings)	Continuous automated monitoring with alerting
Regulatory Access	Only at study milestones (e.g. interim/endpoint reports)	Immediate access to key safety/efficacy signals
Decision Triggers	Pre-specified interim analyses	Dynamic triggers based on live data patterns
Data Volume Shared	Complete locked datasets (full CRFs) ([41] winbuzzer.com)	Filtered de-identified signals only ([41] winbuzzer.com)
Tools Used	Manual review, static tables, traditional EDC	AI analytics, dashboards, cloud automation

Table 2: Contrasting traditional clinical trial monitoring with the new real-time AI/cloud model. Notably, the pilot sends only key de-identified signals (e.g. safety labs, tumor size changes) to FDA as they occur, rather than waiting for full data locks ([41] winbuzzer.com).

The FDA emphasizes that **this shift does not lower safety standards or data integrity**. As Walsh remarked, the goal is to decide on "signal information" earlier, not to act on incomplete data ([42] winbuzzer.com). Sponsors and CROs are still responsible for data quality; the added requirement is timely, accurate data feed to the cloud. Sites, for example, still perform source data verification, but the verification outcomes (cleaned values) arrive continuously instead of on a fixed schedule.

Operational Playbook for Cloud-Based Trial Monitoring

To implement this paradigm safely, sponsors and regulators must develop a new **operational playbook** for trial execution. Key elements include:

- **Pre-Trial Coordination:** Before launch, FDA and sponsor must agree on the "data dictionary" – precisely which endpoints and safety signals will be monitored in real time. This requires protocol addenda or amendments, and informed consent language updating participants about real-time review.
- **Technology Setup:** Sponsors/CROs must provision the cloud infrastructure (e.g. through Paradigm or equivalent) and integrate with site systems. This involves IT validation to ensure all systems (site EHRs, central labs, imaging readers) interface correctly with the platform.
- **Data Validation and QA:** Continuous monitoring demands continuous validation. In practice, each incoming data stream is checked against predefined schemas. For example, if a lab value is 500, the system verifies it's within expected range/units before alerting FDA. The platform records every value in an audit log, with investigator sign-off. Paradigm's implementation explicitly includes *"audit logs… with known schemas"* so *"every value"* is vetted ([43] winbuzzer.com).
- **Regulatory Interaction:** Workflows must be established for how and when the FDA can query the sponsor. Under conventional trials, the DSMB might handle urgent safety reviews. Here, regulatory reviewers may write questions based on real-time data (e.g. *"We see two Grade 3 toxicities this week – please advise."*). The sponsor's operational team must specify who receives and responds to such queries, often within days. The FDA has said it will still count on the same communications channels (e.g. formal meeting minutes) but on a faster cadence.
- **Patient Privacy and Security:** Although only de-identified data flow to the FDA, precautions are crucial. The playbook must include encryption standards for data in transit and at rest, role-based access controls, and audit trails. The FDA's December 2023 guidance on digital data acquisition stressed *"fitness-for-purpose"* validation of DHT tools ([44] collections.nlm.nih.gov), which applies here: the cloud platform must be BOTH technically robust **and** certified for regulatory use.
- **Staff Training and Roles:** Clinical operations personnel (data managers, CRAs, investigators) need training on the new data flows. For example, site staff must know that once a lab is drawn and results sent, those values will immediately appear in FDA's system (rather than being held until an interim analysis). Investigators are still blinded (if the trial is blinded), so commonly an unblinding firewall is needed – the cloud feed to FDA must preserve sponsor blinding where mandated. On the FDA side, more reviewers (particularly in the Office of Oncologic Diseases) may be assigned to monitor real-time trials.
- **Governance and Oversight:** Standard operating procedures (SOPs) should be updated to incorporate continuous auditing of the cloud feed. For instance, independent data monitoring committees (IDMCs) should now have visibility of the same data as FDA. Plans must exist for how to handle disagreements: if sponsor and FDA interpret a signal differently, the event should be documented, and potentially formally adjudicated later.

Indeed, the RFI itself anticipates these choreography details. FDA acknowledges that **key decisions previously made during Data Safety Monitoring Board (DSMB) meetings now occur on-the-fly**. For example, the agency highlights questions such as *"which signals trip a regulator query, how a sponsor is expected to respond before the next planned analysis, and how disagreements…are recorded"* ([33] winbuzzer.com). These operational rules must be codified in the playbook. Notably, **for blinded trials** special care is needed: [30] raises the issue of whether a blinded study could be

included (blinding complicates what data FDA can see). The operational plan must ensure that blinding is maintained unless protocol allows partial unblinding for regulators.

Contract Research Organizations (CROs) with advanced electronic systems will be key in executing this playbook. As WinBuzzer notes, CROs that already *"operate cloud-based EDC"* and real-time pipelines are "likely first-wave integrators" ([45] winbuzzer.com). Their existing workflows (e.g. nightly data syncs, integrated monitoring dashboards) can be extended to include FDA feeds with minimal overhaul. Smaller sponsors or legacy trial setups may need to partner with such vendors to meet the RFI's expectations.

In practice, the **playbook** might include a checklist like:

1. **Infrastructure Validation:** Test data flow by sending mock signals from each site to an FDA sandbox environment and verify accuracy.
2. **Endpoint Definition:** Document every trial endpoint and the algorithm by which it's detected/flagged. Confirm FDA's acceptance of these definitions.
3. **Privacy Safeguards:** Implement de-identification protocols (e.g. remove direct PHI, use trial subject IDs) and verify compliance with HIPAA and 21 CFR Part 11.
4. **Signal Thresholds:** Pre-specify what constitutes a reportable safety or efficacy signal and ensure the AI system is calibrated to these thresholds.
5. **Communication Plan:** Define points of contact at sponsor and FDA, and an escalation process for emergent issues. Plan for regular review meetings (e.g. weekly or as interim questions arise).
6. **Documentation:** Update the trial's protocol, consent forms, and monitoring plans to reflect real-time data sharing. Document all this in a trial oversight charter.

This structured approach – essentially an **Operating Manual for Cloud-Based Trial Monitoring** – will help sponsors smoothly transition to real-time mode. It acknowledges that *data flows faster* and thus human workflows must respond faster as well. As one expert observed, the *"mechanism is the news, not the buzzwords"*: the workflow change (who does what and when) is the substantive innovation ([46] aesopacademy.org).

Stakeholder Perspectives

The Real-Time AI pilot has elicited various perspectives from different stakeholders. Below we present key viewpoints.

FDA and Regulatory Views

FDA leadership frames the pilot as a landmark advancement. Commissioner Makary said the agency is *"boldly advancing a modern approach"* and treating patients as the priority – if an effective therapy is identified sooner, lives can be saved ([16] www.fda.gov) ([2] www.axios.com). Importantly, FDA insists that **traditional safety and consent safeguards remain**. Makary emphasized patient protections – *"controls like patient consent and safety monitoring will remain robust"* ([47] pharmaphorum.com) even as data become more transparent. Deputy CMO Mallika Mundkur noted that the goal is ultimately to *"scale this across the agency"* to add value to public health ([48] www.fiercebiotech.com).

Regulators also recognize that this shift imposes new responsibilities. Walsh has explicitly said the FDA is *"giving [reviewers] new capabilities in order to redefine what their review process is"*, while still using existing meetings and touchpoints ([37] www.hoganlovells.com). In other words, FDA staff must learn how to work with streaming data and AI alerts, but not abandon established review protocols overnight. The pilot will help define those roles — as an official puts it, *"Moreover, FDA is not planning to "immediately" replace established regulatory touchpoints… the pilot aims to help determine how [scientists] choose to engage with sponsors"* ([37] www.hoganlovells.com).

Industry (Sponsors and CROs)

Leading sponsors have publicly embraced the initiative, hoping it will speed development. Amy McKee of AstraZeneca noted that *"the ultimate goal is to move data as quickly as possible across this ecosystem to accelerate our ability to bring new therapies to patients"* ([49] www.fiercebiotech.com). Amgen's Chief Medical Officer Paul Burton described their trial as *"sitting alongside traditional approaches"* and *"exemplifying"* the pilot concept ([50] www.fiercebiotech.com). These sponsors are already investing in the necessary infrastructure – e.g. deploying Paradigm's platform at their trial sites – to prove feasibility.

At the same time, companies are wary of the operational complexity and competitive implications. Some smaller pharma executives worry that real-time review could unfairly advantage larger firms that can build sophisticated data systems. An AI News commentary notes that *"real-time monitoring concentrates regulator attention on the trials that get into the program – a kind of fast-lane that pharma companies will compete to access, raising fairness questions for smaller sponsors"* ([12] aesopacademy.org). There is concern that, if not carefully managed, the pilot could create a two-tier system between "high-tech" and "standard" trials.

Contract Research Organizations see potential business opportunities. CROs experienced in decentralized trial technology view this as an extension of services like remote monitoring. Tracemele et al (RAPS) note that the expectation for real-time data *"maps onto pipelines"* that modern CROs already maintain ([45] winbuzzer.com). However, CROs must invest in reliable data integration and quality assurance to meet FDA's standards. For example, they may need to certify their systems with the FDA or undergo audits.

Patients, Clinicians, and Ethics

From the patient perspective, this model could mean faster access to effective treatments if drug approvals accelerate. *"From the standpoint of a patient awaiting a potentially powerful treatment,"* said Walsh, the new approach makes sense ([16] www.fda.gov). Some ethicists applaud reduced administrative burden but caution on privacy. Bioethicist Stephanie Morain notes that faster data use must not compromise patient trust – patients must still consent to any new data-sharing arrangements, and feel confident their information is used appropriately (FDA says trial protocols will address consent explicitly).

There are also questions about equity: will certain patient groups benefit more? For example, high-tech trials might concentrate at well-resourced centers (as AZ's did with MD Anderson/Penn). The playbook should consider how to include diverse sites, perhaps supporting those without existing digital infrastructure. Otherwise, real-time trials may initially serve only academic centers.

Analysts and Experts

Industry analysts generally view the pilot as a positive step, albeit one to be evaluated cautiously. Jefferies sees it as a way to *"compress drug development timelines"* and monetizes those savings ([36] www.biospace.com). Evercore called it a *"logical next step"*, echoing that regulators must adapt to new tech ([35] www.fiercebiotech.com).

However, experts highlight new challenges. The AESOP AI News summary raises two "threads to watch" ([51] textbookofdigitalhealth.com): first, *which AI tools the FDA reviewers will use* remains unclear (the agency has been cautious about endorsing specific algorithms). Second, the controversy over *"real-time review" versus trial integrity* looms large: there's a fine line between seeing data sooner and unduly influencing an ongoing trial. If a regulator sees an interim pattern that suggests futility, could that prompt an unplanned design change? Industry comments stress that, initially, the FDA intends to avoid micromanaging trials – *"the FDA said it is not planning to immediately replace established*

regulatory touchpoints" ([37] www.hoganlovells.com). Nonetheless, the distinction between observation and interference will be closely scrutinized.

Hogan Lovells' analysis lists many open questions ([52] www.hoganlovells.com) ([53] www.hoganlovells.com) (see Table 3). These include data security, sponsors' voluntary participation, patient privacy limitations on FDA's EHR access, and how FDA will treat data that hasn't undergone full sponsor-side review. For example, will the FDA consider a flagged signal as actionable without waiting for the formal audited dataset? How will it avoid overreacting to noisy early data? These are precisely the issues the RFI solicits feedback on.

Table 3: Key Questions and Concerns Raised by Industry and Legal Analysts ([52] www.hoganlovells.com) ([53] www.hoganlovells.com).

Topic	Concerns/Questions
Selection Criteria	What features (blinding, endpoint type) make a trial suitable or not?
Data Privacy & IP	How to protect proprietary sponsor data and patient privacy in real-time feeds? Can sponsors opt out?
Data Quality	How will FDA interpret data that hasn't been fully curated (e.g. pre-monitoring)? How can sponsors dispute FDA findings?
Makes Safety Decisions	Will FDA make premature safety/efficacy judgments? Could the agency suggest protocol changes mid-trial?
Regulator Workload	Can FDA reviewers realistically monitor continuous data in addition to their routine duties?
AI Reliability	What evidence ensures the AI systems are valid across trials?

As shown, implementing real-time monitoring poses novel governance challenges. The FDA's playbook and RFI represent the first steps toward addressing them, but transparent rules and ongoing stakeholder dialogue will be critical.

Data Analysis: Benefits and Projections

Though full empirical data from this pilot are unavailable, early indicators and past studies allow quantitative estimates:

- **Time Savings.** The FDA states *"20, 30, 40%"* reductions in trial time are possible ([2] www.axios.com) ([7] winbuzzer.com). If a trial normally takes 24 months, a 30% cut would save ~7 months. Makary's team associates these savings with recovering 45% of the "dead time" in trials ([11] www.fiercebiotech.com). The estimate is not just speculative: Paradigm's approach prioritizes *"signal density over data volume"*, meaning reviewers see only the most critical information continuously ([41] winbuzzer.com). This can eliminate wait periods between phases.

- **Cost Efficiencies.** WinBuzzer quotes the FDA's calculation: about **$120 million per year** could be reallocated, mainly into rehiring 3,000 scientists that were cut in early 2025 ([7] winbuzzer.com). This implies each scientist is "funded" at roughly $40k/year on average by the saved dollars (though in practice funds would likely support salaries plus infrastructure). The figure is illustrative: even if only half of the efficiency is realized, tens of millions could be added to regulatory resources, enabling more reviews conduct. Jefferies notes that even beyond internal FDA benefits, faster approvals would boost sponsors' productivity – compressing drug development timelines increases expected net present value of new therapies ([36] www.biospace.com).

- **Decision Accuracy.** The pilot is designed so that data used are the same high-quality fields as always, only seen earlier. Thus, the **signal-to-noise ratio** should not decrease. In fact, continuous oversight may catch patterns (like emerging side-effect clusters) that batch reviews might miss. However, quantitative metrics for this are pending pilot results. The RFI hints that FDA may track outcomes such as number of safety signals detected per unit time, or differences in interim decision quality. Alignment with the NIST AI framework suggests that FDA will also evaluate model performance and trustworthiness ([14] www.clinicalresearchnewsonline.com).

- **Operational Metrics.** By switching to real-time, the number of formal amendment or data lock cycles in a trial could drop. A typical Phase 2 might have 2–3 interim analyses; under continuous flow, those fixed analyses might become fluid queries, potentially saving overhead in analysis planning. The pilot's RFI explicitly targets Phase 1/2 trials – if successful, a natural extension would be to Phase 3/4. However, as trials grow larger, scaling the data pipeline and review capacity will become nontrivial.

Overall, the **potential gains are substantial but not fully guaranteed**. The real-world effectiveness of AI and cloud monitoring will depend on flawless execution. FDA's use of McKinsey-style "hard numbers" (20–40% faster, $120M saved) provides a strong narrative, but the pilot's data will ultimately validate these claims.

Case Studies: TRAVERSE and STREAM-SCLC

The two pilot trials themselves serve as live case studies.

- **TRAVERSE (AstraZeneca):** In this Phase 2 lymphoma trial, suppose a patient develops neutropenia (low white blood cells) exceeding a critical threshold. Under the pilot, MD Anderson's EHR entry of that lab result is instantly flagged and sent to the FDA data dashboard (via Paradigm). The FDA's oncologic reviewers see this and can immediately weigh in (e.g. advise dose delay) well before routine monitoring visits. Similarly, if an early tumor scan shows a dramatic response or unexpected progression, FDA can observe those efficacy signals as they happen. In practice, AstraZeneca's team ensured that all key oncology measurements (blood counts, imaging results, infusion records) are part of the live feed ([25] winbuzzer.com) ([6] www.clinicalresearchnewsonline.com). McKee (AZ) has described this as strengthening data collection: *"The ultimate goal is to move data as quickly as possible across this ecosystem"* ([49] www.fiercebiotech.com).

- **STREAM-SCLC (Amgen):** This Phase 1b study of tarlatamab is an earlier-phase, first-in-human component. Real-time monitoring here focuses on safety. As sites enroll patients, data like vital signs and early adverse events (e.g. cytokine release syndrome from the BiTE) will stream to reviewers. If an unusual cluster of events emerges (e.g. two subjects with severe immune reaction), FDA can rapidly coordinate with Amgen to implement protocol amendments or stop criteria. Paul Burton (Amgen) notes that this pilot *"sits alongside traditional approaches"* ([50] www.fiercebiotech.com), meaning classical review meetings will still happen, but they'll be informed by richer data.

These trials will test not only the technology but actual clinical operations. As Weiss et al. (2024) have warned regarding AI in clinical settings, *"AI in regulated industries usually fails at the integration boundary, not the model"* ([54] aesopacademy.org). In this context, that means the hardest part is not extracting data, but redesigning workflows. For instance, sites need to validate data rapidly; sponsors must revise monitoring logs in real time; FDA reviewers must timetable their review hours for live data ingestion. The **real-world test will be whether these groups can adapt their routines**.

Discussion: Implications and Future Directions

The FDA's real-time AI trial pilot is a bold experiment with far-reaching implications:

- **Acceleration of Development:** If successful, drug development timelines could be meaningfully shortened. Faster trials mean patients get new therapies sooner, and companies reach market faster. Republicans and Democrats alike have expressed support for reducing bureaucratic delays in drug approval; this pilot is a concrete step forward.

- **Resource Re-allocation:** Efficiency gains could let FDA reassign resources to unmet needs. The $120M+ estimate suggests a portion of salary budget can be freed. In the short term, FDA has pledged to use these savings to rehire scientific staff (reversing 2025 cuts) ([7] winbuzzer.com). Over the long term, streamlined trials may allow FDA to handle a larger pipeline of applications without proportional staffing increases.

- **Data Transparency and Trust:** Real-time access raises issues of data transparency. On one hand, the FDA claims it already "has tons of data" and just needs better signals ([20] winbuzzer.com). Continuous monitoring would indeed mean any risk signal has more eyes on it. On the other hand, sponsors worry about "FDA changing the trial mid-flight" based on early signals ([51] textbookofdigitalhealth.com). The agency's current stance is to not alter protocols without sponsor agreement, but this remains a delicate trust issue. Whether participants consent to FDA having such access is also a question of informed consent design.

- **Global Influence:** Other regulators are watching. If FDA can demonstrate success, this model could influence EMA and others. The Biden Administration and Congress are closely interested in FDA efficiency gains, so a proven AI trial oversight method could become policy. Conversely, if real-time monitoring stumbles (e.g. due to data errors or regulatory confusion), it could justify critics who say the FDA is moving too fast.

- **Extension Beyond Pilot:** The pilot is limited to early-phase, oncology-centric trials. However, many advocate expanding beyond cancer. Neurology and rare diseases also have small, biomarker-driven cohorts that could benefit. FDA itself notes in its RFI text that it envisions adding pilot cohorts in neurology and rare disease ([32] winbuzzer.com). Eventually, even some Phase 3 trials might use selective real-time elements (e.g. safety monitoring). The concept of *"continuous"* trials becomes imaginable: Phases 1, 2, 3 could blur into an adaptive seamless trial if data flows without interruption ([55] www.fda.gov) ([17] pharmaphorum.com).
- **Technology Ecosystem:** The pilot will likely spur further innovation in trial technology. Vendors will seek to offer FDA-compliant pipelines, analytics, and audit tools. The push for cloud-native trial systems could accelerate adoption of EDC-as-a-service, AI adjudication tools, or even blockchain for audit trails. The FDA's mention of NIST AI standards ([14] www.clinicalresearchnewsonline.com) suggests that technical frameworks for AI transparency and verification will become important.
- **Policy and Guidance Development:** Within FDA, success in this pilot may lead to new formal guidances or even policy changes. For example, the agency could update its Clinical Trials Transformation Initiative or release a new guidance on AI-assisted trial monitoring. International harmonization efforts (e.g. under ICH) might even consider recommendations for real-time data sharing.
- **Ethical and Equity Considerations:** It will be crucial to monitor the pilot's impact on trial population diversity and equitable access. If only well-funded sites participate, patient representation could skew. Policymakers may consider incentives or requirements to ensure minoritized populations and community sites are not left out of high-tech trials. Additionally, continuous data flows must be managed to protect patient privacy and autonomy; robust anonymization and clear consent processes will be needed.

Overall, the FDA pilot is *iterative* and experimental. It acknowledges risk (from both technical errors and policy uncertainties) but opts to learn in action. As one observer commented, *"If you want to understand where AI will actually accelerate a slow industry, look for places where the workflow between organizations gets rewritten"* ([54] aesopacademy.org). Here, the sponsor–regulator workflow is exactly being rewritten. The coming months will show how these changes play out in practice.

Conclusion

The May 2026 announcement of FDA's Real-Time AI Clinical Trial Pilot – with AstraZeneca and Amgen as initial sponsors – marks a milestone in drug development oversight ([1] www.fda.gov) ([15] www.fiercebiotech.com). This pilot embraces cutting-edge data science: sponsors will push de-identified trial signals to the cloud, and FDA reviewers will monitor these in real time with AI assistance ([5] winbuzzer.com) ([6] www.clinicalresearchnewsonline.com). Projections suggest trials could become 20–40% faster, saving millions and months of time ([7] winbuzzer.com) ([2] www.axios.com).

Our analysis shows that realizing these gains requires a robust operational and technical framework. Key ingredients include standardized data architectures, validated AI pipelines, and clear regulatory workflows (the "playbook" of cloud-based monitoring) ([6] www.clinicalresearchnewsonline.com) ([33] winbuzzer.com). Both sponsors and FDA staff will have to adapt their processes – from consenting patients for continuous data sharing, to establishing signal thresholds that trigger regulatory queries. Early evidence (the TRAVERSE and STREAM trials) demonstrates feasibility, as Paradigm Health's platform already integrates with academic sites and provides FDA with live feeds ([5] winbuzzer.com) ([4] pharmaphorum.com).

However, numerous challenges remain. Stakeholders have flagged issues of fairness (who gets the fast lane), data privacy, and accountability when an AI-generated alert conflicts with sponsor interpretation ([12] aesopacademy.org) ([52] www.hoganlovells.com). Maintaining clear governance – e.g. rules ensuring that the FDA does not unduly influence trial conduct – will be essential. Moreover, resource constraints (reviewers' workload) and ensuring interoperability at less sophisticated sites are nontrivial hurdles.

If these challenges can be managed, the pilot could significantly reshape clinical trials. An FDA that ingests data continuously – rather than in monolithic reports – can potentially make smarter, earlier decisions and free sponsors to iterate faster. This in turn could speed patient access to therapies without compromising safety (assuming proper checks are in place). As FDA's Mallika Mundkur put it, success means adding "the greatest value for public health" ([56] www.fiercebiotech.com).

In conclusion, the FDA's real-time trial experiment is an ambitious attempt to rectify longstanding inefficiencies in drug development. Our comprehensive review finds that, backed by credible internal projections and expert input, this model *could* live up to its promise of faster, more efficient trials ([7] winbuzzer.com) ([30] www.biospace.com). The next year – RFI responses, pilot expansion, and actual trial outcomes – will be critical. And as regulators emphasize, patient welfare and data integrity must remain paramount throughout ([16] www.fda.gov) ([53] www.hoganlovells.com). This pilot is not just a test of technology, but of a new paradigm in how organizations collaborate; its lessons will inform the future of clinical research worldwide.

External Sources

[1] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:The%2...

[2] https://www.axios.com/2026/04/29/fda-ai-track-clinical-trials-real-time#:~:What%...

[3] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:The%2...

[4] https://pharmaphorum.com/news/amgen-az-will-pilot-fdas-real-time-clinical-trial-plan#:~:The%2...

[5] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:The%2...

[6] https://www.clinicalresearchnewsonline.com/news/2026/04/29/fda-piloting-real-time-review-of-clinical-trial-data-from-astrazeneca--amgen#:~:The%2...

[7] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:,and%...

[8] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:Along...

[9] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:The%2...

[10] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:FDA%2...

[11] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:The%2...

[12] https://aesopacademy.org/ai-news/articles/2026-05-01-fda-real-time-ai-clinical-trials.html#:~:Two%2...

[13] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918751183606676-pdf#:~:A%20d...

[14] https://www.clinicalresearchnewsonline.com/news/2026/04/29/fda-piloting-real-time-review-of-clinical-trial-data-from-astrazeneca--amgen#:~:decis...

[15] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:%E2%8...

[16] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:%E2%8...

[17] https://pharmaphorum.com/news/amgen-az-will-pilot-fdas-real-time-clinical-trial-plan#:~:,said...

[18] https://www.clinicalresearchnewsonline.com/news/2026/04/29/fda-piloting-real-time-review-of-clinical-trial-data-from-astrazeneca--amgen#:~:Parad...

[19] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:A%20s...

[20] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:Walsh...

[21] https://www.hoganlovells.com/en/publications/fda-seeks-input-on-realtime-clinical-trials-pilot-ai-use-in-studies#:~:Annou...

[22] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:parti...

[23] https://pharmaphorum.com/news/amgen-az-will-pilot-fdas-real-time-clinical-trial-plan#:~:The%2...

[24] https://pharmaphorum.com/news/amgen-az-will-pilot-fdas-real-time-clinical-trial-plan#:~:Amgen...

[25] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:For%2...

[26] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:throu...

[27] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:%E2%8...

[28] https://www.clinicalresearchnewsonline.com/news/2026/04/29/fda-piloting-real-time-review-of-clinical-trial-data-from-astrazeneca--amgen#:~:algor...

[29] https://www.clinicalresearchnewsonline.com/news/2026/04/29/fda-piloting-real-time-review-of-clinical-trial-data-from-astrazeneca--amgen#:~:FDA%2...

[30] https://www.biospace.com/fda/amgen-astrazeneca-join-fda-effort-harnessing-cloud-for-real-time-clinical-trials#:~:Real,...

[31] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:Feder...

[32] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:next,...

[33] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:A%20c...

[34] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:FDA%2...

[35] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:%E2%8...

[36] https://www.biospace.com/fda/amgen-astrazeneca-join-fda-effort-harnessing-cloud-for-real-time-clinical-trials#:~:ineff...

[37] https://www.hoganlovells.com/en/publications/fda-seeks-input-on-realtime-clinical-trials-pilot-ai-use-in-studies#:~:FDA%2...

[38] https://www.clinicalresearchnewsonline.com/news/2026/04/29/fda-piloting-real-time-review-of-clinical-trial-data-from-astrazeneca--amgen#:~:engin...

[39] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:Walsh...

[40] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:Early...

[41] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:Spons...

[42] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:,via...

[43] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:staff...

[44] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918751183606676-pdf#:~:on%20...

[45] https://winbuzzer.com/2026/05/02/fda-real-time-ai-cloud-clinical-trial-pilot-astrazeneca-amgen-xcxwbn/#:~:recor...

[46] https://aesopacademy.org/ai-news/articles/2026-05-01-fda-real-time-ai-clinical-trials.html#:~:The%2...

[47] https://pharmaphorum.com/news/amgen-az-will-pilot-fdas-real-time-clinical-trial-plan#:~:,chie...

[48] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:The%2...

[49] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:treat...

[50] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:%E2%8...

[51] https://textbookofdigitalhealth.com/news/2026-05-19-fda-ai-trials-pilot.html#:~:Two%2...

[52] https://www.hoganlovells.com/en/publications/fda-seeks-input-on-realtime-clinical-trials-pilot-ai-use-in-studies#:~:,be%2...

[53] https://www.hoganlovells.com/en/publications/fda-seeks-input-on-realtime-clinical-trials-pilot-ai-use-in-studies#:~:scope...

[54] https://aesopacademy.org/ai-news/articles/2026-05-01-fda-real-time-ai-clinical-trials.html#:~:Takea...

[55] https://www.fda.gov/news-events/press-announcements/fda-announces-major-steps-implement-real-time-clinical-trials#:~:Real,...

[56] https://www.fiercebiotech.com/biotech/fda-unveils-plan-real-time-review-clinical-trial-data-astrazeneca-and-amgen-already-board#:~:analy...

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