How Many Clinical Trials Use AI? 2026 ClinicalTrials.gov Census

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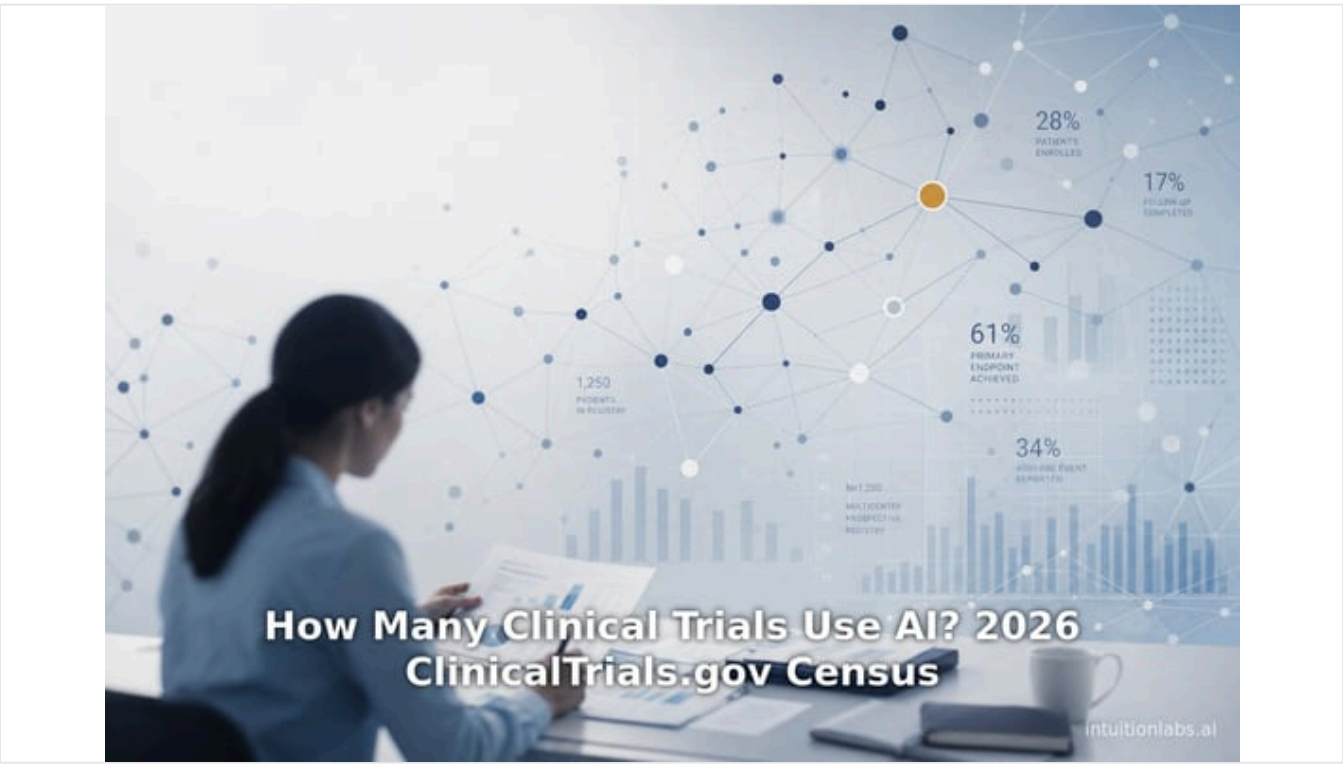

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Executive Summary

The title raises a question with no single official answer: how many clinical trials use artificial intelligence (AI)? This report does not measure all interventional clinical trials that use AI. Its live figures instead measure ClinicalTrials.gov study records returned by specified AI-related keyword searches; the separately reported JMIR cohort uses manual screening and includes both interventional and observational studies. The live-count figures below are a point-in-time snapshot retrieved on August 6, 2026, when the ClinicalTrials.gov API reported a data timestamp of 2026-08-06T09:00:05 (ClinicalTrials.gov API version. In that snapshot, a query against the official **ClinicalTrials.gov** application programming interface (API), the United States registry run by the National Library of Medicine (NLM), returned **4,178 studies** matching the phrase "artificial intelligence" and **2,480 studies** matching "machine learning" out of **597,482 total registered studies** worldwide (Source: clinicaltrials.gov) (Source: clinicaltrials.gov). A broader, deduplicated search combining "artificial intelligence," "machine learning," and "deep learning" returned **6,354 studies** (Source: clinicaltrials.gov), or roughly **1%** of all registered ClinicalTrials.gov studies at that time.

Raw keyword counts, however, capture studies that examine AI as a medical intervention alongside studies that merely mention AI in passing. The most rigorous peer-reviewed accounting comes from a 2024 cross-sectional study published in the *Journal of Medical Internet Research* (JMIR), which applied structured inclusion criteria to identify **3,106 AI/ML-related studies** registered on ClinicalTrials.gov with start dates between January 1, 2010, and December 31, 2023 (Source: pmc.ncbi.nlm.nih.gov). Growth has been sharp and recent: **62.8% of all 3,106 studies (1,951 studies) started between 2021 and 2023 alone** (Source: pmc.ncbi.nlm.nih.gov), up from just 42 trials starting in all of 2015 (Source: pmc.ncbi.nlm.nih.gov). An earlier, independent registry analysis using narrower inclusion criteria found only 358 machine-learning-related studies through the end of 2020, illustrating how sensitive the count is to methodology (Source: pmc.ncbi.nlm.nih.gov).

Of the 3,106 AI/ML studies in the JMIR cohort, 38.4% (1,193) are interventional studies; the remainder are observational studies or observational patient registries. Of the interventional studies, 93% carry no formal drug-development phase because most are devices, diagnostics, or behavioral studies rather than drug trials (Source: pmc.ncbi.nlm.nih.gov). Sponsorship skews heavily toward hospitals and academic medical centers (44.2% and 28% respectively) rather than industry (13.1%) (Source: pmc.ncbi.nlm.nih.gov), and oncology (neoplasms) is the leading therapeutic area at 12.9% of studies, followed by nervous system diseases (12.2%) and cardiovascular disease (11%) (Source: pmc.ncbi.nlm.nih.gov).

Regulators have issued AI-related drug-development guidance and launched related initiatives internationally. The U.S. Food and Drug Administration (FDA) issued its first-ever draft guidance on AI in drug and biological product development in January 2025, disclosing that it has reviewed **more than 500 regulatory submissions containing AI components since 2016** (Source: fda.gov). The European Medicines Agency (EMA) adopted a parallel reflection paper on AI across the medicinal product lifecycle in September 2024 (Source: ema.europa.eu). Outside the United States and European Union, the cited actions are not AI-specific clinical-trial rules: PMDA's Action Plan concerns the agency's own operations (Source: pmda.go.jp); MHRA's AI Airlock is a regulatory sandbox for AI as a medical device (Source: gov.uk); and China's updated Good Clinical Practice guideline adds provisions on new technologies and methods, effective September 1, 2026 (Source: english.nmpa.gov.cn).

Commercially, market researchers estimate the AI-in-clinical-trials software and services market at between $1.20 billion and $2.60 billion in 2024 to 2025, depending on scope, with projections ranging from $2.74 billion by 2030 to as high as $25.52 billion by 2035 (Source: marketsandmarkets.com) (Source: precedenceresearch.com). A separate GlobalData industry survey found 34% of pharmaceutical professionals report function-specific AI deployment, with a further 25% in pilots or proof-of-concept adoption (Source: globaldata.com), while a more conservative 2025 Tufts Center for the Study of Drug Development (CSDD) and Drug Information Association (DIA) survey of 302 industry respondents found that only 10.7% had fully implemented AI/ML on average across 36 clinical trial activities, and 36.9% had not yet begun (Source: pubmed.ncbi.nlm.nih.gov). Named case studies, from Insilico Medicine's rentosertib entering Phase III trials to Mayo Clinic's 80% jump in trial enrollment using IBM Watson, illustrate what AI-enabled trials look like in practice, and major pharmaceutical companies including Pfizer, Novartis, Sanofi, Bayer, Eli Lilly, GSK, and Merck all now run named AI programs touching clinical development, as detailed later in this report (Source: pfizer.com) (Source: investor.lilly.com).

Introduction and Background

Artificial intelligence has moved from a peripheral research topic to a measurable feature of the global clinical trial landscape, but quantifying that shift precisely is harder than it sounds. Unlike drug approvals or trial completions, "AI use" in a clinical trial is not a standardized, mandatory data field on **ClinicalTrials.gov**, the primary U.S. clinical trial registry operated by the National Library of Medicine (NLM), part of the National Institutes of Health (NIH). Instead, any count of "AI clinical trials" is a downstream artifact of search methodology: which keywords are queried, which Medical Subject Headings (MeSH) terms are applied, and which inclusion criteria researchers use to separate trials that genuinely deploy AI from trials that merely mention it in a background paragraph.

ClinicalTrials.gov itself was created following the 1997 Food and Drug Administration Modernization Act (FDAMA), which mandated a public registry for trials studying treatments for serious or life-threatening diseases (Source: nlmdirector.nlm.nih.gov), and NLM launched the site in February 2000 (Source: nlmdirector.nlm.nih.gov). The registry crossed 500,000 registered studies in 2024, its 25th anniversary year, and as of an April 2025 NLM retrospective held more than 530,000 total studies and drew over 2 million monthly visitors (Source: nlmdirector.nlm.nih.gov). ClinicalTrials.gov also participates in the World Health Organization's International Clinical Trials Registry Platform (ICTRP), a global harmonization effort launched in 2006 that, by 2025, comprised a network of 17 Primary Registries worldwide (Source: nlmdirector.nlm.nih.gov). As of this report's live data pull on August 6, 2026, the registry's own statistics API reports **597,482 total registered studies** (Source: clinicaltrials.gov). Against that denominator, even the broadest AI-related keyword search, returning roughly 6,354 studies, represents scarcely more than **1%** of everything ever registered.

That headline number, though, obscures a far more dynamic underlying trend. AI is not spread evenly across the registry's history; it is concentrated overwhelmingly in the last five years, reflecting the broader diffusion of machine learning, deep learning, and, more recently, generative AI into biomedical research. This report treats "how many clinical trials use AI" not as a single fixed statistic but as a **census problem**, and it walks through the registry's own search infrastructure, the best available peer-reviewed cohort studies, market-research estimates, regulatory disclosures, and named case examples to build a defensible, multi-angle answer.

The report proceeds as follows. It first explains the methodological choices that determine which trials get counted as "AI trials." It then presents the current AI trial census using ClinicalTrials.gov's own live search infrastructure, followed by a breakdown of that census by trial phase, sponsor type, and geography, including named industry programs, and then by therapeutic area. A dedicated section reviews the regulatory apparatus, including FDA, EMA, ICH, WHO, and major international regulators, that has emerged around AI in clinical development. A data analysis section aggregates market-size forecasts, industry survey data, and CRO/vendor performance claims on operational AI adoption. Case studies then illustrate what AI-enabled trials look like when they move from registry entries to real drug development programs. The report closes with implications for sponsors,

regulators, and life-sciences technology consultancies advising on AI adoption strategy, such as **IntuitionLabs**, whose advisory practice focuses on "strategic guidance on digital transformation, AI adoption, and technology roadmapping" for pharmaceutical and life-sciences organizations (Source: intuitionlabs.ai).

Methodology: How ClinicalTrials.gov Identifies AI-Related Studies

Any interpretation of the title's question must start by distinguishing ClinicalTrials.gov studies from clinical trials. The registry's official glossary defines a "Clinical trial" (technically an interventional study) as a study "in which participants are assigned to groups that receive one or more intervention/treatment" so that researchers can evaluate the intervention's effects on health outcomes (Source: clinicaltrials.gov). Every study record receives a unique National Clinical Trial (NCT) number in the format "NCT" followed by an 8-digit number, which is the standard identifier used across the registry, the FDA, journals, and third-party trial-matching tools (Source: clinicaltrials.gov).

Crucially, "uses AI" is not itself a structured field in the registry. There is no checkbox a sponsor ticks to declare that a trial involves machine learning. As a result, every count of "AI trials" is produced retrospectively, by searching free-text fields (title, brief summary, detailed description, intervention names) for AI-related terms, or by applying a MeSH-based advanced search filter. This report relies on three distinct measurement approaches, each with different strengths:

- **Live free-text API search**: querying the ClinicalTrials.gov API v2 for exact phrases such as "artificial intelligence," "machine learning," or "deep learning" and reading the `totalCount` field the API returns. Because registry data change, a reproducible report should preserve the full query syntax, retrieval date and time, and the API `dataTimestamp` returned by the version endpoint. This method is fast and current, but it will include trials that mention AI only tangentially (for example, as a comparator or in a discussion of prior literature) and can undercount trials that use domain-specific AI terminology without the phrase "artificial intelligence" itself.
- **Structured MeSH/advanced-search filtering**: an earlier peer-reviewed analysis used ClinicalTrials.gov's advanced search function to filter for studies in which "Machine Learning" had been entered as a formal MeSH-coded term in the report form, restricted to studies first posted on or before December 31, 2020 (Source: pmc.ncbi.nlm.nih.gov). This narrower approach found only 358 eligible studies through 2020, a fraction of what broader keyword searches return for the same period (Source: pmc.ncbi.nlm.nih.gov).
- **Manually screened cohort studies**: the most rigorous approach, exemplified by the 2024 JMIR study, pulls an initial keyword-based candidate set and then has researchers manually exclude irrelevant or duplicate records. That study's initial ClinicalTrials.gov search yielded 3,378 candidate records, of which 272 were excluded after manual review, leaving 3,106 studies for analysis (Source: pmc.ncbi.nlm.nih.gov).

These methodological differences mean the estimates should be reported separately, not as the endpoints of one range. The live keyword result is an all-date registry search as of a stated retrieval date, whereas the JMIR result is a manually screened cohort limited to studies with start dates from 2010 through 2023. Any secondary source citing "the number of AI clinical trials" without specifying its population, period, and search method should be treated cautiously. The FDA's own AI-Enabled Medical Devices List, for comparison, is a related but distinct dataset: as of August 6, 2026, it contains 1,498 listed AI-enabled devices, not clinical trials. The FDA explicitly states the list is "not a comprehensive AI-device resource," since devices are identified "primarily based on the use of AI-related terms in the summary descriptions of their marketing authorization document" (Source: fda.gov). It should not be conflated with trial counts, though it is a useful complementary data point on regulator-facing AI activity.

Census of AI-Related ClinicalTrials.gov Study Records

Using the live-search method described above, this report queried the ClinicalTrials.gov API v2 on August 6, 2026, for each major AI-related search term. These are point-in-time counts of keyword-matching ClinicalTrials.gov study records, not verified counts of interventional trials using AI: the API version response recorded a `dataTimestamp` of 2026-08-06T09:00:05 (ClinicalTrials.gov API version. *Table 1* summarizes those snapshot counts alongside the registry's total study count for context.

SEARCH TERM	MATCHING STUDIES (LIVE COUNT)	SHARE OF ALL REGISTERED STUDIES (597,482 TOTAL)
"artificial intelligence" (exact phrase)	4,178 (Source: clinicaltrials.gov)	approximately 0.70%
"machine learning" (exact phrase)	2,480 (Source: clinicaltrials.gov)	approximately 0.42%
"deep learning" (exact phrase)	1,057 (Source: clinicaltrials.gov)	approximately 0.18%
"AI" (bare term, unquoted)	5,402 (Source: clinicaltrials.gov)	approximately 0.90%
Combined: "artificial intelligence" OR "machine learning" OR "deep learning"	6,354 (Source: clinicaltrials.gov)	approximately 1.06%

Table 1 makes two things clear. First, the bare, unquoted term "AI" returns more hits (5,402) than the precise phrase "artificial intelligence" (4,178), which is expected since "AI" as a two-letter string can appear in acronyms, abbreviations, and unrelated contexts (a known limitation of free-text search that the JMIR cohort study addressed through manual screening). Second, even the most generous combined keyword search, 6,354 studies, represents scarcely more than one in a hundred registered ClinicalTrials.gov studies, reinforcing that AI-labeled records remain a small, fast-growing minority of the registry rather than a mainstream default.

The peer-reviewed, manually screened alternative to this live search is the JMIR cohort of 3,106 AI/ML studies with start dates from 2010 through 2023 (Source: pmc.ncbi.nlm.nih.gov). That study's introduction states plainly that "the number of studies on artificial intelligence (AI) and machine learning (ML) registered on ClinicalTrials.gov has significantly increased since 2016" (Source: pmc.ncbi.nlm.nih.gov), and its year-by-year breakdown quantifies that growth precisely: AI/ML study starts rose from **42 trials in 2015 (1.4% of the cohort)** and **61 in 2016 (2%)** to **81 in 2017 (2.6%)**, then accelerated to **187 in 2018 (6%)** and **255 in 2019 (8.2%)**, before surging to **599 in 2021 (19.3%)**, **672 in 2022 (21.6%)**, and **680 in 2023 (21.9%)** (Source: pmc.ncbi.nlm.nih.gov). In other words, the 599 AI/ML studies that started in 2021 exceeded the count for each individual year from 2015 through 2019, but not the combined 2015-to-2019 total of 626 studies. This growth curve is corroborated independently by the earlier, narrower Zippel and Bohnet-Joschko registry analysis, which found "a continuous rise in ML-related study entries" since 2015, with a particularly sharp jump from 89 studies in 2019 to 149 in 2020 (Source: pmc.ncbi.nlm.nih.gov), a 67% year-over-year increase using a different, more conservative counting methodology.

Despite this growth in registrations, the JMIR study found a persistent transparency gap: only **5.6% (47 of 842) of completed AI/ML studies had posted results on ClinicalTrials.gov** (Source: pmc.ncbi.nlm.nih.gov). That figure matters for anyone using registry counts as a proxy for evidence generation: a trial being registered as "AI-related" says nothing about whether its outcomes were ever made public, a gap regulators and researchers have flagged as a broader reproducibility concern for the AI/ML clinical research literature.

Analysis by Study Type, Phase, Sponsor Type, and Geography

Registering a study as AI-related does not mean it is a conventional drug trial marching through Phase 1 to Phase 4. The JMIR cohort's internal breakdown shows that AI/ML clinical research skews heavily toward device, diagnostic, and behavioral studies rather than formally phased drug trials. *Table 2* below summarizes the phase and sponsor distribution among the cohort's 1,193 interventional studies (38.4% of the full 3,106-study sample) (Source: pmc.ncbi.nlm.nih.gov).

BREAKDOWN	CATEGORY	COUNT / SHARE
Study type	Interventional (of 3,106 total)	1,193 (38.4%)
Formal phase (of 1,193 interventional)	Not applicable (device/diagnostic/behavioral)	1,109 (93%) (Source: pmc.ncbi.nlm.nih.gov)
	Phase 2	28 (2.3%)
	Phase 4	18 (1.5%)
	Phase 3	17 (1.4%)
	Phase 1	7 (0.6%) (Source: pmc.ncbi.nlm.nih.gov)
Sponsor type, reclassified (of 3,106 total)	Hospital/clinic	1,373 (44.2%)
	Academia	869 (28%)
	Industry	407 (13.1%)
	Research institute	156 (5%)
	Individual	151 (4.9%)
	Government	71 (2.3%) (Source: pmc.ncbi.nlm.nih.gov)
FDA-regulated (of 3,106 total)	Device or drug regulated	235 (7.6%) (Source: pmc.ncbi.nlm.nih.gov)
Geography (of 3,106 total)	High-income countries	2,340 (75.3%)
	Upper-middle-income (predominantly China)	675 (21.7%) (Source: pmc.ncbi.nlm.nih.gov)

Table 2 dispels a common assumption: that most AI clinical trials are pharma-sponsored drug studies working through the standard phase-gated approval pathway. Reclassifying ClinicalTrials.gov's broad sponsor categories into more granular subgroups reveals hospitals and clinics as the single largest sponsor category (44.2%), followed by academic institutions (28%), together accounting for over 72% of all AI/ML studies (Source: pmc.ncbi.nlm.nih.gov). Industry-sponsored trials, at 13.1% of the cohort, remain a distinct minority relative to hospital and academic sponsorship combined.

This pattern helps explain the low FDA-regulated share (7.6%): most AI/ML clinical research on the registry consists of investigator-initiated studies validating diagnostic algorithms, clinical decision-support tools, or screening models at individual hospitals and academic medical centers, rather than pivotal, FDA-regulated drug or device trials intended for a marketing submission. Geographically, the concentration in high-income countries (75.3%) alongside a substantial upper-middle-income contingent (21.7%, driven largely by China) mirrors broader global patterns in AI research output, though it leaves lower-income and lower-middle-income countries starkly underrepresented in the registered AI/ML trial base.

Industry sponsors that do appear in the AI/ML trial base include large pharmaceutical companies running formal collaborations with AI-focused biotechs and technology vendors. AstraZeneca, for example, expanded a three-year AI drug discovery collaboration with BenevolentAI in January 2021 to cover systemic lupus erythematosus and heart failure, building on their original 2019 partnership (Source: benevolent.com), and separately committed $18 million for the initial phase of a September 2024 collaboration with Immunai to apply AI-driven immune-system modeling to dose selection, mechanism-of-action analysis, and biomarker identification in clinical research (Source: contractpharma.com).

Named Industry Sponsors: How Major Pharmaceutical Companies Use AI in Trials

Beyond AstraZeneca's collaborations detailed above, most large pharmaceutical companies now run named, publicly disclosed AI programs touching clinical trial operations, even though, as shown in Table 2, industry sponsors represent only 13.1% of registered AI/ML studies. **Pfizer** used a machine-learning tool called Smart Data Query (SDQ) during its COVID-19 vaccine trial, and reported that trial data was "ready to be reviewed a mere 22 hours after meeting the primary efficacy case counts" (Source: pfizer.com), compared with a typical 30-plus-day manual data-cleanup process. **Novartis** Pharmaceuticals Canada funded a clinical trial using Innodem Neurosciences' AI-powered eye-tracking software to help diagnose and monitor multiple sclerosis progression (Source: novartis.com).

Sanofi states that AI is "already helping Sanofi find better trial locations, recruit the right patients faster" and, in some cases, lets it simulate outcomes using virtual "digital patient twins" to skip unnecessary trial phases (Source: sanofi.com). **Bayer** has run a three-year Future Clinical Trials program with Aalto University and Helsinki University Hospital investigating how AI could build a "virtual" control group from medical databases, reducing the number of patients who must be assigned to placebo (Source: pharmaphorum.com).

Eli Lilly launched TuneLab, an AI and machine-learning platform giving biotech companies access to drug-discovery models built on Lilly research data obtained "at a cost of over $1 billion" (Source: investor.lilly.com), and separately struck a $2.75 billion deal with Insilico Medicine, the company behind rentosertib, which has "developed at least 28 drugs using generative AI tools" (Source: cnbc.com). **GSK** expanded its collaboration with Tempus, the same AI trial-matching company profiled in the Case Studies section, in a deal built around de-identified patient data intended to speed enrollment and improve trial design, which GSK says "will contribute to GSK's R&D success rate and provide patients with more personalised treatment" (Source: gsk.com). **Merck** built an internal generative-AI platform for writing clinical study reports (CSRs) that cut first-draft production time "from an average of 180 hours to 80 hours" while reducing errors (Source: merck.com).

These disclosures reinforce the earlier finding that industry AI activity is concentrated less in trial registration itself and more in the operational layer around trials: recruitment (Pfizer, Sanofi), diagnostic and monitoring tools (Novartis), statistical design (Bayer), platform licensing (Eli Lilly), data partnerships (GSK), and clinical documentation (Merck).

Analysis by Therapeutic Area

Beyond phase and sponsor type, the JMIR cohort study's therapeutic-area breakdown reveals where AI/ML research is concentrated clinically. Oncology (coded as "Neoplasms") leads all condition categories, accounting for **12.9% (420 of 3,106) of AI/ML studies** (Source: pmc.ncbi.nlm.nih.gov), consistent with oncology's long-standing role as an early adopter of computational and imaging-driven diagnostic tools, from tumor-detection algorithms to treatment-response prediction models. Nervous system diseases follow closely at **12.2% (395 studies)**, and cardiovascular diseases account for **11% (356 studies)** (Source: pmc.ncbi.nlm.nih.gov), reflecting the maturity of AI-based imaging and signal-processing tools in radiology, neurology, and cardiology.

A second tier of therapeutic areas rounds out the picture: respiratory tract diseases account for **8.5% (275 studies)**, digestive system diseases for **7.8% (253 studies)**, and mental disorders for **6.7% (219 studies)** (Source: pmc.ncbi.nlm.nih.gov). Together, these six leading categories, oncology, neurology, cardiovascular disease, respiratory disease, gastroenterology, and psychiatry, account for approximately 62% of the listed AI/ML study-category counts, meaning AI clinical research is not evenly distributed across medicine but concentrated in specialties where imaging, physiological signals, or large longitudinal datasets make algorithmic pattern-recognition especially tractable.

This concentration pattern is echoed in market-research segmentation of the commercial AI-in-clinical-trials sector, which tracks functional use cases including patient recruitment, trial design optimization, data management and quality control, adverse event prediction and detection, drug repurposing, and regulatory compliance as distinct market segments (Source: marketsandmarkets.com), and Precedence Research's July 2026 market update identifies the pharmaceutical industry as the largest end-user segment of AI-in-clinical-trials technology as of 2025 (Source: precedenceresearch.com). Notably, oncology's dominance in the registered-trial count is consistent with, though not identical to, its dominance as a target area for named AI-discovery programs at companies such as Recursion Pharmaceuticals and Insilico Medicine, discussed later in the Case Studies section.

Regulatory Landscape for AI in Clinical Trials

Regulatory attention to AI in clinical trials has intensified sharply since 2023, producing a mix of discussion papers, draft nonbinding guidance, reflection papers, and other regulatory initiatives across major jurisdictions. The FDA's Center for Drug Evaluation and Research (CDER) issued its first draft guidance specifically addressing AI in drug and biological product development, titled "Considerations for the Use of Artificial Intelligence to

Support Regulatory Decision-Making for Drug and Biological Products," in January 2025 under Docket Number FDA-2024-D-4689 (Source: fda.gov). The agency described it plainly: "This is the first guidance the agency has issued on the use of AI for the development of drug and biological products" (Source: fda.gov), and then-FDA Commissioner Robert Califf stated that AI has "transformative potential to advance clinical research and accelerate medical product development to improve patient care" (Source: fda.gov).

The guidance introduces a **risk-based credibility assessment framework** for evaluating trust in an AI model's performance for a specific "context of use" (COU), rather than endorsing any particular AI technique wholesale (Source: fda.gov). Notably, it explicitly excludes AI used solely for drug discovery or for internal operational efficiencies that do not bear on patient safety, drug quality, or study reliability (Source: fda.gov), meaning AI-discovered drugs like those discussed in the Case Studies section below are governed by this framework only once AI outputs begin informing clinical trial design, endpoint assessment, or safety monitoring, not at the earlier discovery stage. FDA disclosed that its experience already includes **more than 500 drug and biological product submissions containing AI components since 2016** (Source: fda.gov), and that the guidance was informed by a Duke-Margolis expert workshop in December 2022 and **more than 800 public comments** received on two FDA discussion papers published in May 2023 (Source: fda.gov). The same day, FDA also issued a separate draft guidance on AI-enabled medical device software functions, reflecting coordinated policy activity across its device and drug centers (Source: fda.gov). CDER's own resource page also lists a January 2026 publication titled "Guiding Principles of Good AI Practice in Drug Development" among its selected AI-related guidance materials, indicating continued regulatory activity into 2026 (Source: fda.gov).

The European Medicines Agency moved on a parallel track. Its "Reflection Paper on the Use of Artificial Intelligence in the Medicinal Product Lifecycle" was adopted by the Committee for Medicinal Products for Human Use (CHMP) on September 9, 2024, and by the Committee for Medicinal Products for Veterinary Use (CVMP) two days later (Source: ema.europa.eu), following a public consultation that ran from July 19 to December 31, 2023 (Source: ema.europa.eu). EMA's paper covers AI/ML use "at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting" (Source: ema.europa.eu), and it takes a notably prescriptive stance on clinical trials specifically: "The use of AI/ML within the context of clinical trials should meet applicable requirements in the ICH E6 guideline for good clinical practice (GCP)" (Source: ema.europa.eu). Rather than creating an AI-specific GCP standard, EMA folds AI oversight into the existing framework, though with a significant documentation burden: for high-risk, not-previously-qualified AI/ML models, EMA states that "the full model architecture, logs from model development, validation and testing, training data and description of the data processing pipeline would likely be considered parts of the clinical trial data or trial protocol dossier" at marketing authorization or GCP inspection (Source: ema.europa.eu). Underlying this is a stated principle that "a human-centric approach should guide all development and deployment of AI and ML" across the product lifecycle (Source: ema.europa.eu).

At the international harmonization level, ICH has not yet issued a standalone AI-specific GCP guideline, but its E6(R3) Annex 2 Concept Paper, endorsed by the ICH Management Committee on April 28, 2023, explicitly acknowledges that "the growing exploration and use of artificial intelligence offers the potential to significantly enhance evidence generation in clinical trials" (Source: database.ich.org), signaling that AI-related GCP considerations will likely be woven into future ICH guidance on decentralized trials, pragmatic trial designs, and real-world data sources rather than addressed in an isolated document.

The World Health Organization has also weighed in, though from an ethics and governance angle rather than a trial-approval one. WHO's January 2024 guidance on large multi-modal models (LMMs) identifies "scientific research and drug development, including to identify new compounds" as one of five core health applications of generative AI (Source: who.int), and the guidance contains more than 40 recommendations for governments, technology companies, and healthcare providers (Source: who.int). WHO's Dr. Alain Labrique, Director for Digital Health and Innovation, framed the stakes bluntly: "Governments from all countries must cooperatively lead efforts to effectively regulate the development and use of AI technologies, such as LMMs" (Source: who.int). Taken together, this regulatory record shows that AI oversight for clinical trials has moved from informal discussion (FDA's 2023 discussion papers, EMA's 2023 consultation) to formal guidance (FDA's and EMA's 2024 to 2025 documents) in roughly two years, a pace that outstrips the underlying statistical growth in AI/ML trial registrations described in the previous sections.

International Regulatory Approaches: Japan, the United Kingdom, China, and Canada

Regulatory attention to AI in clinical trials is not confined to the United States and Europe. **Japan's** Pharmaceuticals and Medical Devices Agency (PMDA) has adopted an official Action Plan governing AI use, stating that "the PMDA will proactively utilize artificial intelligence (AI) technologies. We have developed the Action Plan for Use of AI in Operations" (Source: pmda.go.jp).

The **UK's** Medicines and Healthcare products Regulatory Agency (MHRA) has taken a distinctly experimental approach with its "AI Airlock" regulatory sandbox, launched in Spring 2024 specifically for AI-powered medical devices (Source: gov.uk). MHRA selected five innovative technologies for the program's first pilot cohort in December 2024 (Source: gov.uk), and a second testing phase, completed in May 2026, covered seven innovators across

three regulatory challenges (Source: gov.uk). The programme has since secured a £3.6 million multi-year funding boost to expand beyond its pilot phase (Source: gov.uk).

China's National Medical Products Administration (NMPA) jointly issued an updated Good Clinical Practice (GCP) guideline for drugs, effective September 1, 2026, which "updates the previous version that had been in effect since 2020" and adds new provisions on data governance and the application of new technologies and methods in clinical studies (Source: english.nmpa.gov.cn) (Source: english.nmpa.gov.cn). A peer-reviewed comparative analysis published in *npj Digital Medicine* (a Nature-family journal) found that China's regulatory approach to AI in medical technology diverges from the standards-oriented approaches used in the US and EU, noting that "NMPA has specifically pointed out that they would not make a strict distinguishment between AI and ML to medical devices" (Source: nature.com), and the same analysis identified 59 AI-enabled medical devices approved in China as of July 2023 (Source: nature.com), a figure consistent with this report's earlier finding that upper-middle-income countries, predominantly China, host 21.7% of registered AI/ML clinical studies.

Health Canada, meanwhile, has integrated AI directly into its own trial registry infrastructure rather than only regulating sponsors' use of it: the agency's clinical trials search portal uses AI to match Canadian trial records to international registry entries, and "at the time the portal was launched, about 17% of trials were matched using AI" (Source: canada.ca). Taken together, the cited examples show national regulators moving from passive observation to active experimentation with AI governance frameworks within a similar 2023-to-2026 window. They do not establish whether any jurisdiction worldwide has finalized binding, AI-specific clinical-trial regulation.

Data Analysis and Evidence

Quantifying AI's footprint in clinical trials also requires looking beyond registry counts to the commercial and operational data that describe how sponsors and vendors are actually deploying AI. Three independent market-research firms have published estimates of the "AI in clinical trials" software and services market, and while their figures diverge, they agree on the direction and rough order of magnitude. *Table 3* summarizes these estimates.

RESEARCH FIRM	BASE-YEAR MARKET SIZE	FORECAST VALUE	FORECAST YEAR	CAGR
MarketsandMarkets	$1.20 billion (2023) / $1.35 billion (2024)	$2.75 billion	2030	12.5% (Source: marketsandmarkets.com)
MarketsandMarkets (Dec. 2024 release)	$1.20 billion (2023)	$2.74 billion	2030	12.4% (Source: prnewswire.com)
Precedence Research (July 2026 update)	$2.60 billion (2025)	$25.52 billion	2035	25.66% (Source: precedenceresearch.com)
Grand View Research (2021 estimate)	not specified in 2021 base year	$5.2 billion	2028	21.7% (Source: prnewswire.com)

The spread in these numbers, from a 2030 forecast of $2.74 billion to a 2035 forecast of $25.52 billion, is explained mostly by differing scope (narrower "clinical trial software" definitions versus broader "AI-based clinical trial solutions" definitions that include services) and differing forecast horizons rather than genuine disagreement about trajectory; all three firms report double-digit to mid-twenties percentage CAGRs, confirming a market growing several times faster than overall healthcare information technology (IT) spending. Precedence Research's July 2026 update also found that North America held the dominant regional share and that the pharmaceutical industry was the largest end-user segment of the AI-in-clinical-trials market in 2025 (Source: precedenceresearch.com).

Market-size growth, however, measures vendor revenue and spending intent, not actual organizational maturity. A 2025 peer-reviewed survey conducted by the Tufts Center for the Study of Drug Development (Tufts CSDD) in partnership with the Drug Information Association (DIA) offers a more sobering adoption picture: the survey gathered **302 responses assessing levels of AI/ML implementation across 36 distinct clinical trial planning, execution, and regulatory-submission activities** (Source: pubmed.ncbi.nlm.nih.gov). On average across those 36 activities, **36.9% of respondents were not yet using AI/ML at all, 30.3% were beginning or piloting it, 22.1% were partially implementing it, and only 10.7% had**

fully implemented it (Source: pubmed.ncbi.nlm.nih.gov). Read alongside the market-size projections, this survey suggests that the "AI in clinical trials" market is currently driven more by early pilots and vendor contracts than by mature, fully operationalized deployment, a distinction relevant to sponsors evaluating build-versus-buy decisions and to consultancies advising on adoption roadmaps.

An August 2024 FDA and Clinical Trial Transformation Initiative (CTTI) workshop report catalogs where AI is already operationally embedded in drug development, citing use cases such as "optimizing trial site selection, automating image analysis for disease scoring, enabling remote patient monitoring" (Source: pmc.ncbi.nlm.nih.gov), a list that maps closely onto the therapeutic-area concentrations documented earlier in this report. Vendor-reported efficiency claims add further texture, though they should be read as vendor-disclosed figures rather than independently audited benchmarks. Medidata, a clinical trial technology unit of Dassault Systèmes, reported in its Second Annual AI Report (May 2026) that **72.9% of "Early Adopters"** (organizations with 18 or more months of AI experience) saw a reduction in clinical trial timelines, 67.5% saw a reduction in protocol deviations, and 82% of surveyed organizations expected a two-to-threefold return on investment (ROI) from AI clinical trial solutions (Source: medidata.com). Contract research organization (CRO) ICON plc reports that its AI-powered "One Search" site-selection tool is associated with "up to a 26% increase in subject recruitment" and "a 24% improvement in hitting first-patient-in targets" on its own capability pages (Source: iconplc.com), while IQVIA's September 2025 Clinical Trial Financial Suite, an agentic-AI platform automating trial budgeting and invoicing, projects customer outcomes of "up to 50% reduction in processing time" (Source: ir.iqvia.com).

CRO and clinical technology vendors have begun publishing their own quantified AI performance claims directly on their websites, offering another data point beyond the market-size forecasts above. The following Parexel figures are company-reported claims, not independently audited effectiveness benchmarks. **Parexel**, a large CRO, has committed to public principles for AI governance, stating it will "outline our six principles for how Parexel conceives, develops, deploys, and monitors AI applications intended for use in clinical development" (Source: parexel.com), and reports that "AI capabilities are delivering 60% cycle time reductions in IND submission generation" (Source: parexel.com), that its "site identification optimizer has decreased site selection timelines by 50%, removing it from the critical path of study start-up" (Source: parexel.com), and that "AI-enabled case processing delivers 20+ efficiency gains in expectedness assessments, literature case processing, and handle times" (Source: parexel.com). The company also reports deploying "nearly 50 robotic process automation (RPA) bot solutions" across its clinical workflows (Source: parexel.com), and in a May 2026 launch of its "ParexelAI" suite described delivering a "50% reduction in site selection process timelines" using generative AI (Source: globenewswire.com).

Other clinical AI vendors report similarly specific, if vendor-disclosed, claims. **Saama**, a clinical data analytics company, states it "has trained over 90 AI models on more than 300 million life sciences-specific data points to handle the unique demands of clinical research" (Source: saama.com). **Unlearn.AI**'s digital-twin methodology, PROCOVA, has moved beyond vendor claims to formal regulatory recognition: the company states its "digital twins-based method was officially qualified by the European Medicines Agency for use in Phase 2 and 3 trials with continuous outcomes" (Source: unlearn.ai), and that its technology is "built to meet regulatory-grade compliance standards, including GxP, 21 CFR Part 11, and SOC 2 Type 2" (Source: unlearn.ai). **Veeva Systems**, a major clinical and regulatory software provider, has built "Vault AI Agents" that "operate within Veeva applications and have deep application-specific prompts and safeguards" (Source: veeva.com), embedding AI directly into the clinical trial management systems many sponsors already use. **Thermo Fisher Scientific**, whose PPD unit is one of the largest CROs by trial volume, announced what it called a "landmark collaboration with OpenAI to embed advanced artificial intelligence across its clinical trials business" in October 2025 (Source: corporate.thermofisher.com).

Independent survey data broadly corroborates the direction, if not always the magnitude, of these vendor claims. A **GlobalData** industry survey conducted in mid-2026 found that "of the 157 pharmaceutical professionals surveyed, 34% report function-specific AI deployment within their organizations, with a further 25% in pilots or proof-of-concept adoption" (Source: globaldata.com), and the same survey found clinical trial design and recruitment was the second most-cited high-value AI use case, behind only drug discovery: "followed by clinical trial design and recruitment at 45%, and then medical writing at 41%" (Source: globaldata.com). Separately, IQVIA cited a cross-industry survey finding that 73% of industry participants surveyed reported "spectacular" or "significant" improvements in core operational processes from using vendor applications embedded with AI (Source: iqvia.com). These figures sit meaningfully above the Tufts CSDD/DIA survey's 10.7% full-implementation rate cited earlier, a gap likely explained by GlobalData's and IQVIA's broader, less strictly defined categories of "deployment" and "improvement" compared with Tufts CSDD/DIA's activity-by-activity implementation scale.

Case Studies and Real-World Examples

Registry counts and market forecasts describe the aggregate picture; the following cases illustrate what "a clinical trial that uses AI" actually looks like in practice, spanning AI-discovered drugs now in late-stage trials, AI-assisted patient recruitment, and AI-enabled biomarker analysis.

Insilico Medicine's Rentosertib: From AI Discovery to Phase III

Insilico Medicine, a generative-AI drug discovery company, developed **rentosertib** (also known by its earlier code names ISM001-055 and INS018_055) using its Pharma.AI platform, which the company describes as a medicine "whose target was identified with AI, whose chemical structure was designed with generative AI" (Source: prnewswire.com). The drug targets TNIK, a novel fibrosis target identified through Insilico's AI-driven target discovery approach, and its Phase IIa results, published in *Nature Medicine* in June 2025, were described by the company as "the industry's first proof-of-concept clinical validation of AI-driven drug discovery" (Source: prnewswire.com). In that Phase IIa trial (registered as **NCT05938920**, sponsored by Insilico Medicine Hong Kong Limited and now completed) (Source: clinicaltrials.gov), the 60 mg once-daily rentosertib arm produced a mean forced vital capacity (FVC) change of **+98.4 mL, compared to a mean decline of -20.3 mL in the placebo group** across 71 idiopathic pulmonary fibrosis (IPF) patients at 22 sites in China (Source: prnewswire.com). The FDA granted rentosertib Orphan Drug Designation for IPF in February 2023 (Source: prnewswire.com), and on July 7, 2026, Insilico announced initiation of a Phase III trial expected to enroll 320 patients across 47 centers in China, becoming the company's first asset to reach Phase III and, by the company's account, one of the first fully AI-discovered and AI-designed drugs to reach a pivotal registration trial (Source: prnewswire.com).

Recursion Pharmaceuticals' REC-4881: AI Phenomics in a Rare Disease Trial

Recursion Pharmaceuticals discovered **REC-4881**, a MEK1/2 inhibitor, using AI-driven high-content cellular phenomics: unbiased, image-based screening of cell models designed to identify phenotypic "rescue hits" in APC-deficient (adenomatous polyposis coli) disease models, the company stated that "using high-content cellular phenomics driven by AI, REC-4881 emerged as one of the strongest phenotypic rescue hits" (Source: ir.recursion.com). The molecule was in-licensed from Takeda and redirected toward familial adenomatous polyposis (FAP), a rare hereditary condition. In the ongoing Phase 1b/2 TUPELO trial, announced December 8, 2025, Recursion reported preliminary results in which the 4 mg once-daily dose achieved a **43% median reduction in total polyp burden after 12 weeks**, with **75% of evaluable patients showing reductions** (Source: ir.recursion.com). In the same company-reported preliminary dataset, 12 weeks after stopping therapy, **82% of evaluable patients (9 of 11) maintained a reduction** in polyp burden, with a 53% median reduction from baseline (Source: ir.recursion.com). In its May 2026 first-quarter update, Recursion said it had initiated FDA engagement on a potential registration path and expected to provide an update in the second half of 2026 (Source: ir.recursion.com).

Exscientia's DSP-1181: The First AI-Designed Drug in Human Trials

In January 2020, **Sumitomo Dainippon Pharma** (now Sumitomo Pharma) and AI drug-design company **Exscientia** announced that DSP-1181, a candidate for obsessive-compulsive disorder (OCD) created using Exscientia's Centaur Chemist AI platform, had entered Phase I clinical trials in Japan, an event widely described as the world's first AI-designed drug to reach human trials: "a phase I clinical study of DSP-1181, that was created using Artificial Intelligence (AI), has been initiated in Japan for the treatment of obsessive-compulsive disorder" (Source: sumitomo-pharma.com). The companies reported that the AI-driven exploratory research phase took **less than 12 months to complete, compared with a typical average of 4.5 years using conventional research techniques** (Source: sumitomo-pharma.com), at least a 4.5-fold faster timeline when compared with 12 months. This company-reported comparison helped establish the commercial case for AI-driven small-molecule design that later companies, including Insilico and Recursion, have built upon.

Mayo Clinic and Tempus: AI-Driven Trial Matching in Oncology

Beyond drug discovery, AI has become embedded in the operational mechanics of running trials, particularly patient recruitment. **Mayo Clinic** deployed **IBM Watson for Clinical Trial Matching** in its oncology practice and, over an 11-month period, saw an **80 percent increase in enrollment** to its systemic therapy clinical trials for breast cancer (Source: healthtechmagazine.net). Mayo oncologist Tufia Haddad, physician leader for the project, said the tool "enabled all patients to be screened for all available clinical trial opportunities" (Source: healthtechmagazine.net), a direct answer to the labor-intensive, manual chart-review process that historically limited trial screening capacity. Separately, precision-medicine company **Tempus** operates the **TIME network**, an AI-enabled clinical trial matching program that, over a six-month period from July to December 2023, spanned 94 sites and 840,523 patients across 74 trials, and generated 71 trial activations and 189 patient consents (Source: tempus.com), averaging more than one patient consent per day, with algorithmic activation times of 14.4 days for just-in-time matching and 38.8 days for prospective matching (Source: tempus.com).

Roche and PathAI: AI-Powered Biomarker Analysis at Trial Scale

Roche and **Bristol Myers Squibb (BMS)** announced a collaboration in March 2022 in which a PathAI-developed AI algorithm for CD8 biomarker analysis was integrated into Roche's NAVIFY Digital Pathology software, with the companies stating the "AI-powered algorithm will be used by Bristol Myers Squibb to analyse clinical trial samples that have been stained with Roche's CD8 assay and generate quantitative spatial biomarker data" (Source: prnewswire.com). Roche subsequently agreed to acquire PathAI outright, announced May 7, 2026, for $750 million upfront plus up to $300 million in contingent milestones, stating that "PathAI's strength in AI-driven solutions, including clinical trial support and translational research, will complement Roche's deep expertise in companion diagnostics" (Source: roche.com). For Roche, the progression from a biomarker-algorithm licensing deal in 2022 to its announced 2026 acquisition of PathAI illustrates one company's move from a vendor collaboration to a proposed internal capability.

Iambic Therapeutics, insitro, and Isomorphic Labs: AI-Native Biotechs Reach the Clinic

A wave of AI-native biotechs beyond Insilico and Recursion has also begun reaching clinical trials. **Bayer** announced a small-molecule drug discovery collaboration with **Iambic Therapeutics** in June 2026, citing the industry-wide reality that "more than 90 percent of candidates fail in clinical trials" as the rationale for applying Iambic's AI-based molecular optimization earlier in the discovery process (Source: iambic.ai). Iambic's own AI-discovery platform had already reached the clinic by that point: the company dosed the first patient in a Phase 1 trial of **IAM1363**, an AI-discovered HER2 inhibitor for solid tumors, describing it as "the First Program from Iambic's Leading AI-Driven Drug Discovery Platform to Commence Human Studies" (Source: iambic.ai).

insitro, an AI-native biotech founded by Daphne Koller, partnered with Eli Lilly in September 2025 "to develop advanced machine learning models" predicting small-molecule pharmacological properties, expanding an existing relationship that already spanned siRNA delivery and antibody discovery (Source: insitro.com). And **Isomorphic Labs**, the drug-discovery company spun out of Alphabet's Google DeepMind, is preparing to start its first human clinical trials for AI-designed drugs following a $600 million funding round, with reporting indicating "Isomorphic is prioritizing oncology candidates for its first clinical trials" (Source: chemdiv.com). Together with Insilico Medicine and Recursion Pharmaceuticals profiled above, these programs indicate that AI-native drug discovery is transitioning from a venture-funded research thesis into an emerging clinical-stage category with named human-trial programs; the development-stage and performance claims in these examples should be interpreted according to their underlying registry records, regulator documents, peer-reviewed publications, or company disclosures.

(Hypothetical Example) A Mid-Size Sponsor's AI Adoption Roadmap

(Hypothetical Example) Consider a mid-size specialty pharmaceutical company preparing its first AI-enabled Phase 2 oncology trial. It could assess whether AI-assisted site selection or patient matching is appropriate for its protocol, evaluate vendors' evidence in the context of its own trial, and plan for governance, validation, and staff training. If the model will generate information intended to support FDA regulatory decision-making on safety, effectiveness, or quality, the sponsor should discuss the proposed context of use and evidence plan with FDA as appropriate. FDA's January 2025 risk-based credibility framework remains draft, nonbinding guidance and is not a settled documentation requirement (Source: fda.gov).

Implications and Future Directions

The data assembled in this report point to several converging implications for sponsors, regulators, and technology advisors. First, the gap between registry-level keyword-matching study-record counts (roughly 4,000 to 6,000 records, or about 1% of the total registry) and the much larger market-size and vendor-adoption figures suggests that AI's footprint in clinical development may extend beyond what public registry text captures. That is, AI is increasingly embedded in how trials are run (site selection, patient matching, data management, biomarker analysis) even in trials that would not be flagged as "AI trials" by a keyword search of their public registry summary. This mismatch means keyword-based trial counts, including the ones presented in this report's own Table 1, likely understate AI's true operational penetration into the clinical trial enterprise, while cohort studies restricted to trials that formally study or deploy AI as an intervention likely represent a lower, more conservative bound.

Second, the concentration of AI/ML trial sponsorship in hospitals and academic medical centers (72% combined) rather than industry (13%) suggests that much of the registered AI/ML clinical research base reflects algorithm validation studies, often for diagnostic or clinical decision-support tools, rather than pivotal drug trials. FDA's risk-based credibility framework is still draft, nonbinding guidance, while EMA's reflection paper describes how existing GCP requirements apply to AI/ML. Whether industry sponsorship will grow disproportionately remains uncertain and should not be inferred from these materials alone.

Third, the regulatory pace itself, from FDA's May 2023 discussion papers to its January 2025 draft guidance, from EMA's 2023 consultation to its September 2024 reflection paper, and from MHRA's Spring 2024 AI Airlock launch to China's September 2026 GCP update, has been faster than many prior digital-health regulatory transitions, suggesting global regulators view AI in clinical trials as a near-term priority rather than a speculative future concern. FDA's disclosure of more than 500 submissions containing AI components since 2016 indicates that CDER has experience reviewing such material. However, FDA's framework remains draft, nonbinding guidance and does not itself establish a requirement to invest in AI capability or predict a sponsor's competitive position.

Fourth, the divergence between vendor-reported efficiency claims (ICON's 26% recruitment increase, Parexel's 50 to 60% cycle-time reductions (Source: globenewswire.com), Medidata's 72.9% of early adopters reporting timeline reductions) and the more conservative Tufts CSDD/DIA finding that only 10.7% of organizations have fully implemented AI across their trial activities is itself informative: it indicates a market in which early, well-resourced adopters are seeing meaningful gains, while the broader industry lags. For life-sciences organizations evaluating where to invest, this gap argues for treating vendor-reported percentages as best-case outcomes achievable with sustained, multi-year commitment rather than results attainable from a single pilot project. Consultancies advising on this transition, including firms such as IntuitionLabs, which positions its practice around "digital transformation, AI adoption, and technology roadmapping" for pharmaceutical and life-sciences organizations, are likely to see continued demand precisely because the survey data shows most organizations are still early in this maturity curve rather than having already solved the adoption problem internally (Source: intuitionlabs.ai).

Additional operational examples reinforce this picture. Unlearn.AI's digital-twin reanalysis of a completed Phase 2 Alzheimer's disease trial found that a conventional statistical analysis would have required 23% more trial participants, adding up to an estimated five months of enrollment, without the digital-twin method (Source: unlearnai.substack.com), a concrete illustration of the statistical-efficiency argument behind AI-driven synthetic control arms. Novartis has pursued a parallel path with Amazon Web Services (AWS) and Accenture, building an AI-enabled clinical trial data platform aimed at "reducing clinical trial development cycles by at least six months" (Source: zenml.io).

Looking forward, three trends bear watching. Generative AI's role in protocol design and synthetic control arms is likely to expand as regulators clarify acceptable statistical methodologies for AI-augmented control arms, particularly given Unlearn.AI's EMA qualification for Phase 2 and 3 trials with continuous outcomes. Second, if sponsors use AI models to produce data or information intended to support regulatory decisions on safety, effectiveness, or quality, later-stage programs such as rentosertib, REC-4881, and IAM1363 could offer relevant examples of how FDA's January 2025 draft credibility framework operates in practice. AI use in drug discovery alone is outside that framework's scope. Third, given that 75.3% of AI/ML trials currently originate in high-income countries and 21.7% in upper-middle-income countries (predominantly China), and given China's own regulatory activity through its September 2026 GCP update, expect increasing attention to whether AI-enabled trial infrastructure, and the diagnostic and recruitment tools it powers, diffuses to lower-income settings or further concentrates clinical research capability in already well-resourced regions.

Frequently Asked Questions (FAQs)

How many ClinicalTrials.gov studies mention AI as of 2026? A live, all-date ClinicalTrials.gov keyword search for "artificial intelligence," "machine learning," or "deep learning" combined returned 6,354 studies on August 6, 2026 (Source: clinicaltrials.gov), about 1.06% of the 597,482 studies then listed in the registry (Source: clinicaltrials.gov). Separately, a peer-reviewed, manually screened cohort identified 3,106 AI/ML-related studies with start dates from 2010 through 2023 (Source: pmc.ncbi.nlm.nih.gov). These are different estimates, not a numerical range, because they use different periods and inclusion rules. Only 38.4% of the manually screened cohort were interventional studies, so that cohort should not be read as an exclusively interventional-trial count.

How does ClinicalTrials.gov's AI search work? The registry does not have a dedicated "AI trial" filter; users search free text or use MeSH-coded advanced search terms like "Machine Learning," and results depend heavily on the exact search term and syntax used, which is why this report presents a range of counts across multiple search methodologies rather than a single figure.

Which trial phases have the most AI-related trials? Among interventional AI/ML studies, 93% carry no formal phase designation because they are devices, diagnostics, or behavioral interventions (Source: pmc.ncbi.nlm.nih.gov); among those with a formal phase, Phase 2 is most common (2.3% of interventional studies) (Source: pmc.ncbi.nlm.nih.gov).

Which sponsors are most common in the JMIR AI/ML study cohort? Hospitals and clinics sponsor the largest share of those studies (44.2%), followed by academic institutions (28%), with industry sponsors accounting for 13.1% (Source: pmc.ncbi.nlm.nih.gov).

Which therapeutic areas are most common in the JMIR AI/ML study cohort? Oncology leads at 12.9% of AI/ML studies, followed by nervous system diseases (12.2%) and cardiovascular disease (11%) (Source: pmc.ncbi.nlm.nih.gov).

Has AI in clinical trials grown over time? Yes, sharply: 62.8% of all AI/ML studies in the JMIR cohort started between 2021 and 2023 alone, versus just 42 studies starting in 2015 (Source: pmc.ncbi.nlm.nih.gov).

Which pharma companies use AI in clinical trials? Named examples in this report include Insilico Medicine (rentosertib), Recursion Pharmaceuticals (REC-4881), Sumitomo Pharma with Exscientia (DSP-1181), Pfizer, Novartis, Sanofi, Bayer, Eli Lilly, GSK, Merck, and AstraZeneca (with BenevolentAI and Immunai), among others discussed in the Case Studies and Analysis sections.

What is the market size for AI in clinical trials? Estimates range from $1.20 billion to $2.60 billion for 2023 to 2025, depending on the research firm's scope, with forecasts ranging from $2.74 billion by 2030 to $25.52 billion by 2035 (Source: marketsandmarkets.com) (Source: precedenceresearch.com).

Do regulators outside the United States and European Union have AI-specific clinical trial rules? The cited examples show relevant regulatory initiatives, not established AI-specific clinical-trial rules. PMDA's Action Plan governs its own use of AI in operations (Source: pmda.go.jp); MHRA's AI Airlock is a sandbox for AI as a medical device (Source: gov.uk); China's updated GCP guideline includes new-technology and method provisions, effective September 2026 (Source: english.nmpa.gov.cn); and Health Canada uses AI to match records in its trial-search portal (Source: canada.ca).

Which CROs and technology vendors offer AI-powered clinical trial tools? Named examples include Parexel, whose ParexelAI suite reports a "50% reduction in site selection process timelines" (Source: globenewswire.com), as well as Saama (Source: saama.com), IQVIA, ICON, whose One Search tool reports "up to a 26% increase in subject recruitment" (Source: iconplc.com), Medidata, whose Second Annual AI Report found "72.9% of 'Early Adopters' are now seeing a reduction in clinical trial timelines" (Source: medidata.com), Veeva Systems (Source: veeva.com), Unlearn.AI, and Tempus, all discussed in the Data Analysis and Case Studies sections above.

What role do AI-native biotechs play in clinical trials? Companies including Insilico Medicine, Recursion Pharmaceuticals, Exscientia, Iambic Therapeutics (Source: iambic.ai), insitro (Source: insitro.com), and Isomorphic Labs (Source: chemdiv.com) have moved from AI-only discovery platforms to companies running or entering their own named human clinical trials, detailed in the Case Studies section.

Conclusion

There is no single correct answer to "how many clinical trials use AI." The report's two principal estimates should not be treated as the endpoints of one census: the all-date live keyword search returned 6,354 ClinicalTrials.gov records on August 6, 2026, whereas the peer-reviewed, manually screened cohort identified 3,106 AI/ML-related studies with start dates from 2010 through 2023. They have different populations, periods, and inclusion rules. What is unambiguous across the registry analyses is the trajectory: the JMIR cohort's annual AI/ML study starts rose from double digits before 2017 to hundreds by 2021. Regulatory infrastructure has also developed quickly: FDA and EMA issued AI-focused materials, while ICH adopted the final E6(R3) Annex 2 Good Clinical Practice guideline in June 2026. Annex 2 applies to evolving technologies as relevant but is not an AI-specific standard; national regulators in Japan, the UK, China, and Canada have also issued relevant guidance, operated sandboxes, or adopted AI-enabled regulatory tools.

The composition of that growth matters as much as its magnitude. In the JMIR 2010-2023 ClinicalTrials.gov cohort, AI/ML studies were disproportionately hospital- and academic-sponsored rather than industry-sponsored, concentrated in oncology, neurology, and cardiovascular disease, and mostly non-phased (device, diagnostic, and behavioral studies rather than formally phased drug trials). At the same time, named industry case studies, from Insilico Medicine's rentosertib entering Phase III to Recursion's REC-4881 showing durable clinical activity in a rare disease trial to Iambic Therapeutics dosing its first Phase 1 patient, demonstrate that AI-discovered and AI-designed therapeutics are no longer a speculative category but an active, if still small, part of the late-stage pipeline, backed by named commitments from Pfizer, Novartis, Sanofi, Bayer, Eli Lilly, GSK, and Merck. Operational AI, in patient recruitment, site selection, and biomarker analysis, appears more broadly diffused than trial-design-level AI, based on the gap between conservative registry counts and more expansive vendor and market-research figures, though the Tufts CSDD/DIA survey's finding that only 10.7% of organizations have fully implemented AI across their trial activities is a useful corrective against overstating how far that operational diffusion has actually progressed. For sponsors, regulators, and advisory firms alike, the clearest takeaway is that any reported count must state whether it covers keyword-matching registry study records, manually screened AI/ML studies, or interventional trials. The consequential question is how rigorously AI use is validated, documented, and regulated as it moves from pilot to broader practice.

Tags: ai clinical trials, clinicaltrials.gov, artificial intelligence clinical trials, machine learning clinical trials, clinical trial statistics 2026, ai drug discovery, clinical trial regulation, ai in pharma, clinical trial technology

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