How Many FDA Submissions Use AI? CDER's Review Findings

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Executive Summary

The **U.S. Food and Drug Administration (FDA)**'s **Center for Drug Evaluation and Research (CDER)** has documented a rapid, sustained rise in the number of drug and biologic regulatory submissions that reference artificial intelligence (AI) or machine learning (ML). CDER's own peer-reviewed landscape analysis found that in 2016 and 2017, agency staff identified only one such submission per year, but by 2021 that count had jumped to 132, roughly a tenfold increase over 2020 (Source: doi.org) (Source: doi.org). CDER officials have since disclosed progressively larger cumulative totals as the count kept climbing: over 300 submissions with AI components as of a May 2024 presentation (Source: fda.gov), more than 500 CDER submissions and more than 560 **Center for Biologics Evaluation and Research (CBER)** submissions from 2016 through the January 2025 draft guidance (Source: medcentral.com), and more than 800 **CDER** submissions with AI components according to a peer-reviewed 2026 analysis (Source: nature.com).

This growth prompted the FDA to issue its **first-ever guidance document specifically on AI use in drug development**, the January 2025 draft guidance "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products," which the agency itself describes as marking new regulatory ground: "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). The draft guidance describes a seven-step, risk-based "credibility assessment framework" that may be used to establish and evaluate the credibility of an AI model's output for a specific "context of use" (COU), while explicitly declining to favor any particular AI methodology, since a Troutman Pepper Locke legal analysis of the guidance found it "does not endorse the use of any specific AI approach or technique" (Source: troutman.com). Notably, the guidance explicitly excludes AI used purely for drug discovery or internal operational efficiency, focusing instead on AI that touches the nonclinical, clinical, postmarketing, and manufacturing phases of the drug product life cycle (Source: fda.gov).

Internally, CDER has built out governance and tooling to manage this volume. A center-wide **AI Council**, formed in 2024, consolidated three previously separate AI groups into one oversight body (Source: firstwordpharma.com), while the agency-wide generative AI tool **Elsa** launched on June 2, 2025 to help staff "accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets" (Source: fda.gov). By May 2026, FDA reported that generative AI adoption among staff had grown "from just 1% in early 2025 to over 80% today" (Source: nextgov.com), though independent reporting from CNN and Ars Technica also documented internal complaints that Elsa's rollout was "rushed, buggy, overhyped, and inaccurate" and that the tool has "made up nonexistent studies" during review work (Source: arstechnica.com) (Source: cnn.com).

Placed in context, CDER receives roughly 1,500 initial Investigational New Drug (IND) applications per year (Source: ovid.com) and approves roughly 47 novel drugs annually (Source: raps.org), meaning AI-referencing submissions, while growing fast in relative terms, still represent a modest fraction of overall CDER intake, concentrated heavily in clinical-stage IND filings rather than final marketing applications (Source: cersi.umd.edu). This report examines those numbers, the regulatory framework FDA built around them, the internal tools and governance CDER uses to process AI-enabled submissions, and named real-world examples, including Insilico Medicine's AI-designed rentosertib, Recursion Pharmaceuticals' REC-1245, Iambic Therapeutics' IAM1363, and Absci's ABS-101, of how AI is entering the regulated drug pipeline as of August 2026.

Introduction and Background

Artificial intelligence has moved from a peripheral curiosity in pharmaceutical research to a documented feature of the regulatory submissions that FDA's **CDER** reviews every year. The question "how many FDA submissions use AI" does not have one static answer because public disclosures include both annual counts and cumulative totals reported at different points in time. Each figure must therefore be read according to its stated reporting period, cutoff date, and scope. Understanding those numbers also requires understanding how FDA defines and counts an "AI-enabled" submission, which submissions are in scope (INDs, New Drug Applications, Abbreviated New Drug Applications, and Biologics License Applications), and how the count has evolved as AI, and especially generative AI, has become more embedded in both industry drug development and the agency's own internal review processes.

This report is organized around CDER's own disclosures. It traces the count from the first peer-reviewed FDA-authored landscape analysis in 2022, which found essentially zero AI-referencing submissions in 2016 and 2017 and then explosive growth by 2021 (Source: doi.org), through a succession of larger cumulative figures FDA officials have disclosed in conference presentations, interviews, and formal guidance documents through 2026. It also covers the regulatory apparatus FDA has since constructed around this growth, most notably the January 2025 draft guidance on AI credibility assessment, the 2023 discussion papers that preceded it, and internal governance structures such as CDER's AI Council and the agency-wide **Elsa** generative AI tool.

The distinction between AI used **by industry** in a regulatory submission and AI used **by FDA** to review that submission is central to this topic and is frequently conflated in public discussion. CDER's headline submission counts refer to the former: sponsors incorporating AI or ML models into drug discovery, nonclinical research, clinical trial design, safety signal detection, or manufacturing quality control, then describing that AI use in their regulatory filings. Elsa and related internal tools, by contrast, refer to FDA's own use of generative AI to help its reviewers process the resulting workload, a separate but related trend covered later in this report.

This report also situates CDER's numbers alongside a related, larger, and more mature dataset: FDA's Center for Devices and Radiological Health (CDRH) has authorized more AI-enabled medical devices than CDER has AI-referencing drug submissions, a useful point of comparison given that the device pathway has existed since 1995 and now numbers in the thousands (Source: medtechdive.com). The sections that follow examine CDER's review process and examples of AI-enabled applications, using FDA disclosures alongside peer-reviewed and trade-press reporting current as of August 2026.

How FDA Tracks AI Use in Regulatory Submissions

CDER does not have a formal, real-time public dashboard of "AI submissions." Instead, its count comes from periodic internal database searches that agency scientists have described in peer-reviewed literature, conference slide decks, and interviews. The foundational methodology traces to a 2022 paper published in *Clinical Pharmacology & Therapeutics*, co-authored by FDA scientists, which searched CDER's internal databases "for submissions with key terms 'machine learning' or 'artificial intelligence' in Center for Drug Evaluation and Research (CDER) internal databases for Investigational New Drug applications, New Drug Applications, Abbreviated New Drug Applications, and Biologic License Applications" (Source: doi.org). This full-text, keyword-based search approach is important to note: it captures any submission in which a sponsor's own filing text mentions AI or ML terminology, not necessarily every submission that uses an AI model internally without describing it as such, meaning the true figure could be an undercount if sponsors under-disclose, or an overcount if the terms appear incidentally.

That 2022 study found that AI/ML-referencing submissions rose from just one per year in 2016 and 2017 to 132 in 2021 (Source: doi.org), a finding later reproduced in a CDER conference slide deck by FDA's Office of Medical Policy that broke the count down by submission type. That table shows **IND** filings rising from 1 (2016) to 128 (2021), while combined **NDA, ANDA, and BLA** filings, the later-stage marketing applications, stayed in the low single digits throughout the same period, reaching only 2 by 2021 (Source: cersi.umd.edu) (Source: cersi.umd.edu). The same presentation showed that the growth was overwhelmingly concentrated in the clinical research stage of development, rising from 1 submission in 2016 to 118 by 2021 (Source: cersi.umd.edu), rather than in earlier discovery-stage or later postmarket-stage filings.

This methodology matters for interpreting every subsequent number in this report. When CDER officials cite "over 300," "over 500," or "over 800" cumulative submissions, they are describing a running keyword-search total across years, not an annual snapshot, and different disclosures were made at different points using data current only through that disclosure's own cutoff date. FDA's discussion paper process reinforces this: the agency's May 2023 discussion paper "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products" was issued jointly by CDER, CBER, and CDRH specifically "to facilitate a discussion with stakeholders on the use of artificial intelligence (AI) and machine learning (ML) in drug development to help inform the regulatory landscape in this area" (Source: govinfo.gov), and the document itself is explicit that it "is not FDA guidance or policy, and is not meant to endorse a specific AI/ML use or approach in drug development" (Source: govinfo.gov). That paper was later revised in February 2025 to reflect the intervening growth in submissions and public comment (Source: fda.gov).

The Core Numbers: CDER's AI Submission Counts From 2016 to 2026

A growth timeline can be reconstructed from CDER's public disclosures when each figure is anchored to its stated reporting period and the date it was made public. *Table 1* below distinguishes annual counts from cumulative figures.

Table 1. Publicly disclosed AI- or ML-referencing submission counts, labeled by reporting center and disclosure date

DISCLOSURE DATE	REPORTED FIGURE	SOURCE AND CONTEXT
2016 to 2017 (as reported 2022)	**1 submission per year**	FDA-authored landscape analysis in *Clinical Pharmacology & Therapeutics* (Source: doi.org)
2018 (as reported 2023)	**3 submissions**	CDER official Hao Zhu, cited by RAPS: "only three submissions contained AI/ML components" (Source: raps.org)
2021 (as reported 2022)	**132 submissions**, approximately 10x the 2020 count	FDA-authored *Clinical Pharmacology & Therapeutics* analysis (Source: doi.org)
2022 (as reported July 2023)	**170 submissions received that year**	CDER's Hao Zhu, cited by RAPS (Source: raps.org)
Mid-2023 (cumulative, as of July 2023)	**Over 175 submissions**	FDA's Tala Fakhouri in a Federal News Network interview (Source: federalnewsnetwork.com)
Mid-2024 (cumulative since 2016)	**Over 300 submissions**	Fakhouri interview and CDER's May 2024 conference slide deck (Source: europeantech.news) (Source: fda.gov)
November 2024 (cumulative since 1995, drugs/biologics only)	**Over 300 submissions** for drugs and biologics with AI components	Then-Commissioner Robert Califf at FDA's inaugural Digital Health Advisory Committee meeting (Source: endpoints.news)
January 2025 (cumulative, 2016 to 2023)	**Over 500 CDER submissions; over 560 CBER submissions**	FDA statement to trade press accompanying the draft AI guidance (Source: medcentral.com)
February 2026 (CDER cumulative since 2016)	**Over 800 CDER submissions** with AI components	Peer-reviewed *npj Digital Medicine* analysis (Source: nature.com)

Table 1 shows a figure that has grown consistently over nearly a decade, but the reader should treat each number as a snapshot rather than a precisely comparable annual series: the "over 300" figure appears in both a mid-2024 interview and a November 2024 Commissioner statement, while the "over 500" figure from January 2025 covers a similar 2016-to-2023 window, suggesting some of the apparent jumps reflect refinements in counting methodology, newly indexed submissions, or simply rounding in public remarks rather than only new submission volume. What is not in dispute across the sources is the direction of growth: from roughly one submission a year in 2016 and 2017 to 132 reported submissions in 2021 and 170 reported submissions in 2022, with later disclosures reporting larger cumulative totals. The available public disclosures do not establish several hundred submissions in a single year. Growth was driven overwhelmingly by clinical-stage IND filings referencing AI or ML in some capacity (Source: cersi.umd.edu). CDER's May 2024 presentation also broke the over-300 cumulative figure down by therapeutic area, finding oncology submissions were the largest single category (Source: fda.gov), a pattern independently corroborated by RAPS' reporting that of the 132 submissions received in 2021, "most or 27% were in the oncology space, followed by 15% in psychiatry and 12% in gastroenterology" (Source: raps.org).

FDA's Regulatory Framework for AI in Drug and Biologic Submissions

The submission growth documented above did not occur in a regulatory vacuum indefinitely. FDA's first formal step toward a policy response was a pair of 2023 discussion papers. The first, focused specifically on manufacturing, was "Artificial Intelligence in Drug Manufacturing," filed under Docket No. FDA-2023-N-0487, with the agency requesting comments and information "by May 1, 2023" (Source: thefederalregister.org). The second, broader paper, "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products," was issued jointly with CBER and CDRH in May 2023 under Docket No. FDA-2023-N-0743, with comments due "by August 9, 2023" (Source: govinfo.gov). FDA disclosed that this discussion paper drew "over 800 comments from 65 different organizations" (Source: europeantech.news), a volume of stakeholder engagement that directly informed the agency's subsequent guidance.

That guidance arrived on **January 7, 2025**: "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products," jointly issued by CDER, CBER, CDRH, the Center for Veterinary Medicine, the Office of Clinical Pharmacology, and other FDA offices (Source: hhs.gov). FDA describes it plainly as a first: "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-Commissioner Robert Califf framed its purpose as "providing an agile, risk-based framework that promotes innovation and ensures the agency's robust scientific and regulatory standards are met" (Source: fda.gov). FDA's own justification for issuing the guidance now, rather than earlier, cites the submission growth directly: "Since 2016, the use of AI in drug development and in regulatory submissions has exponentially increased" (Source: fda.gov). The agency confirmed the guidance itself is grounded in its accumulated review experience, "aligning with the agency's experience in evaluating over 500 submissions involving AI components since 2016" (Source: pharmexec.com).

The guidance's central mechanism is a **seven-step, risk-based credibility assessment framework** that sponsors use, in dialogue with FDA, to establish confidence in an AI model's output for a specific "context of use," or COU (Source: fda.gov). Legal analysis of the document has similarly characterized it as establishing "a 'risk-based credibility assessment framework' for use by industry and FDA" (Source: faegredrinker.com). The framework applies across what FDA calls the "drug product life cycle," defined to include "nonclinical, clinical, postmarketing, and manufacturing phases," but the guidance is explicit that drug discovery itself falls outside its scope, stating that "the use of AI for the purposes of drug discovery is not in the scope" of the document (Source: fda.gov). The guidance likewise states it "does not address the use of AI models (1) in drug discovery or (2) when used for operational efficiencies (e.g., internal workflows, resource allocation, drafting/writing a regulatory submission)" (Source: fda.gov), meaning the credibility framework is narrowly aimed at AI outputs that could affect a regulatory decision on safety or efficacy, not every AI tool a sponsor might use somewhere in its business.

To illustrate the framework in practice, FDA's guidance walks through two hypothetical contexts of use: a clinical example, "the sponsor is exploring a strategy to use an AI model to stratify patients for 24-hour inpatient monitoring based on their risk" of an adverse reaction, and a manufacturing example involving AI-based visual analysis of vial fill volumes (Source: fda.gov). Underlying all of this is FDA's definition of AI itself, borrowed directly from Executive Order 14110: "AI is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions" (Source: content.govdelivery.com), a definition that CDER, CBER, CDRH, and the Office of Clinical Pharmacology adopted jointly in a March 2024 cross-center paper describing their coordinated approach to AI oversight across the medical product life cycle.

Table 2 below summarizes selected FDA AI-related drug and biologic policy documents and principles through January 2026.

Table 2. FDA's AI-related drug and biologic policy documents, in chronological order

DOCUMENT	DATE	SCOPE AND KEY FEATURE
Discussion Paper: Artificial Intelligence in Drug Manufacturing	Docket opened February 2023, comments due May 1, 2023	CMC/manufacturing-specific AI use cases; not binding guidance (Source: thefederalregister.org)
Discussion Paper: Using AI and ML in the Development of Drug and Biological Products	Issued May 11, 2023; comments due August 9, 2023	Joint CDER/CBER/CDRH paper spanning discovery through postmarket surveillance; drew 800+ comments from 65 organizations (Source: govinfo.gov) (Source: europeantech.news)
Cross-center paper on AI across the medical product life cycle	March 2024	Adopted a shared AI definition from Executive Order 14110 across CBER, CDER, CDRH, and OCP (Source: content.govdelivery.com)
Draft Guidance: Considerations for the Use of AI to Support Regulatory Decision-Making for Drug and Biological Products	Issued January 7, 2025	First formal AI guidance for drug/biologic submissions; 7-step credibility assessment framework; excludes discovery-stage and operational-efficiency AI (Source: hhs.gov) (Source: pda.org)
Revised Discussion Paper: Using AI and ML in the Development of Drug and Biological Products	Revised February 2025	Updated version of the 2023 paper reflecting subsequent submission growth and public comment (Source: fda.gov)
Guiding Principles of Good AI Practice in Drug Development	January 2026	CDER and CBER collaborated with EMA on 10 principles for AI in drug and biological-product development, including human-centric design, risk-based use, data governance, lifecycle management, and clear essential information (Source: fda.gov)

As *Table 2* shows, FDA moved from discussion papers to a January 2025 draft guidance and, in January 2026, published joint FDA/EMA good-AI-practice principles. The draft guidance remains Draft Level 1 guidance, is not for implementation, and contains nonbinding recommendations.

Industry reaction to the January 2025 draft guidance has been broadly constructive but has pressed FDA for more specificity. The International Society for Pharmaceutical Engineering's formal comment letter stated that it "commends the FDA for its well-structured and clear guidance" on AI model credibility assessment (Source: ispewebassets.org), while PharmaVoice's coverage of the guidance's reception found that, notwithstanding that praise, "many are still left wanting more" specificity from the agency (Source: pharmavoice.com). RAPS reporting on formal stakeholder comments found the Biotechnology Innovation Organization pressing FDA on how the credibility framework should apply given that "sponsors often use third-party vendors, which are the entities that develop, train, and maintain the AI models" (Source: raps.org), while the Pharmaceutical Research and Manufacturers of America went further, proposing its own version of the credibility steps and urging that "FDA include the definitions of other key terms in the Draft Guidance" (Source: raps.org).

Inside CDER's AI Review Infrastructure

Parallel to the external-facing guidance process, CDER built internal governance and, more recently, internal AI tooling to manage the reviewer-side workload created by rising AI-related submissions. In August 2024, then-CDER Director Patrizia Cavazzoni established a unified **AI Council**, described as "the consolidation of the agency's activities regarding the technology into a single AI Council" that folded in three previously separate bodies: an AI Steering Committee, an AI Policy Working Group, and an AI Community of Practice (Source: firstwordpharma.com). Cavazzoni linked the reorganization directly to submission trends, stating that "the scope and impact of AI use in drug development are expanding" (Source: firstwordpharma.com). The council was co-led by three named CDER officials: "Sri Mantha, head of CDER's Office of Strategic Programs, Tala Fakhouri, associate director of data science and AI policy, and Qi Liu," overseeing innovation and partnerships (Source: endpoints.news). By mid-2025, reporting indicated FDA planned to layer on two additional cross-agency councils, one on internal AI use and training and one on AI policy for regulated products, both chaired by the agency's Chief AI Officer (Source: venable.com).

The most visible piece of FDA's internal AI infrastructure is **Elsa**, a generative AI tool the agency launched agency-wide on June 2, 2025, "designed to help employees" across scientific review, inspection, and administrative functions (Source: fda.gov). Commissioner Marty Makary described an accelerated rollout: "Following a very successful pilot program with FDA's scientific reviewers, I set an aggressive timeline to scale AI agency-wide by June 30" (Source: fda.gov), a claim Reuters corroborated, quoting Makary that "today's rollout of Elsa is ahead of schedule and under budget" (Source: reuters.com). FDA states it is already "using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets" (Source: fda.gov), and FDA's Chief AI Officer Jeremy Walsh called the launch "the dawn of the AI era at the FDA," a quote Ars Technica also carried in its own coverage of the rollout (Source: arstechnica.com). The tool runs in "a high-security GovCloud environment" and FDA states it does not train on data submitted by regulated industry (Source: fda.gov).

Elsa's adoption has grown quickly by FDA's own account: a May 2026 update reported the agency planned "to scale up employee use of generative AI from just 1% in early 2025 to over 80% today," alongside the rollout of "Elsa 4.0" and a consolidated internal data platform called **HALO**, which merged "more than 40 disparate application and submission data sources, systems and portals across all FDA centers" (Source: nextgov.com) (Source: globenewswire.com). That growth has not been without controversy. Ars Technica reported that FDA staff privately characterized the rollout as "rushed, buggy, overhyped, and inaccurate" (Source: arstechnica.com), while BioSpace similarly described the tool's debut as a "clunky launch of Elsa, an AI tool to increase efficiency, has sparked concern" both inside and outside the agency (Source: biospace.com). In July 2025, three current or former FDA employees told reporters that Elsa "hallucinates confidently," with one saying "anything that you don't have time to double-check is unreliable" (Source: engadget.com), and CNN separately reported that the tool has "made up nonexistent studies" or misrepresented research during actual review work (Source: cnn.com). Commissioner Makary responded that he had "not heard those specific concerns" when asked by CNN, while also noting that Elsa use remains voluntary for staff (Source: engadget.com). Separately, then-HHS Secretary Robert F. Kennedy Jr. framed the broader rollout in sweeping terms, declaring that "the AI revolution has arrived" across federal health agencies (Source: cnn.com).

Beyond Elsa, CDER operates two programs directly relevant to how sponsor-side AI tools enter the regulatory pipeline. The **Innovative Science and Technology Approaches for New Drugs (ISTAND)** program, in operation since November 2020, qualifies novel drug development tools, including AI-based ones, for use across multiple development programs. As of July 2025, "ISTAND has accepted eight submissions: three AI-based tools, two tools that assess preclinical safety without using animals" and others (Source: fda.gov), and FDA stated that "based on this high number of acceptances, ISTAND will transition to a permanent program" from its original pilot status (Source: fda.gov). Separately, CDER's **Emerging Drug Safety Technology Program (EDSTP)** focuses specifically on AI and other emerging technology use in pharmacovigilance, with one of its three stated goals being to "serve as the central point of contact for discussion between industry and CDER on the use of AI and other emerging technologies in PV" (Source: fda.gov).

Analysis of Key Segments: Therapeutic Areas, Submission Stages, and Drugs Versus Devices

Breaking CDER's AI submission count down by segment reveals a lopsided distribution across three dimensions: submission type, development stage, and therapeutic area. On submission type, CDER's own year-by-year table shows the growth is almost entirely an **IND phenomenon**. IND filings, made when a sponsor wants to begin or continue clinical testing, rose from 1 in 2016 to 128 by 2021, while combined NDA, ANDA, and BLA filings, the applications that seek marketing approval, moved only from roughly zero to 2 over the same period (Source: cersi.umd.edu) (Source: cersi.umd.edu). This gap matters for interpreting the headline numbers: most of what CDER is calling an "AI submission" is a sponsor telling FDA, at the investigational stage, that it used an AI or ML tool somewhere in discovery, biomarker analysis, or trial design, not a final marketing application built around an FDA-cleared AI-based drug.

By development stage, the same CDER table shows clinical research submissions dominating, rising from 1 to 118 over 2016 to 2021, while the categories tracked for discovery, preclinical, and postmarket stages remained comparatively small throughout (Source: cersi.umd.edu). This tracks with the guidance's own scope, which a Troutman Pepper Locke analysis noted "does not endorse the use of any specific AI approach or technique" and instead centers on the clinical, postmarketing, and manufacturing phases where FDA's data show submissions are actually concentrated (Source: troutman.com); the numeric data confirm that clinical-stage AI use, not discovery-stage AI use, is where the growth is concentrated in CDER's own accounting, even though public attention often focuses on AI-driven drug discovery platforms.

By therapeutic area, oncology consistently leads. CDER's May 2024 presentation broke its 300-plus cumulative AI submissions down by therapeutic category with oncology as the largest single group, a pattern that matches RAPS' independent reporting that "27%" of the 132 submissions received in 2021 were oncology-related, "followed by 15% in psychiatry and 12% in gastroenterology" (Source: raps.org).

Finally, CDER's drug-submission figures and CDRH's AI-enabled device list should not be treated as a single measure of FDA's AI-related regulatory workload, because they count different regulatory units. At the agency's first Digital Health Advisory Committee meeting in November 2024, then-Commissioner Califf stated that "the agency since 1995 has received more than 1,000 submissions for AI-enabled medical devices, more than 300 submissions for drugs and biologics with AI components" (Source: endpoints.news). By 2026, CDRH's public AI/ML-Enabled Medical Device List had grown considerably larger still, showing "1 to 50 of 1,524 entries" as of the most recent list update in March 2026 (Source: fda.gov), and a peer-reviewed cross-sectional analysis found that CDRH's "annual authorization volume increased from a mean of 1.8 per year between 1995 and 2014 to 264 per year between 2023 and 2025, with 331 authorizations recorded in 2025" (Source: doi.org). The figures show that FDA publicly tracks AI-enabled devices through a product-level marketing-authorization list and separately reports CDER drug and biologic submissions using AI components. Because those are different units and have different inclusion methods, they do not establish a direct numerical comparison between device and drug activity.

Data Analysis and Evidence

The submission-count trend sits inside a much larger AI-in-pharma market and adoption pattern. On market size, Grand View Research's own industry report estimates the global AI-in-drug-discovery market "was estimated at USD 2.35 billion in 2025 and is projected to reach USD 13.77 billion by 2033," implying a compound annual growth rate of roughly 24.8% (Source: grandviewresearch.com). A separate MarketsandMarkets forecast, released via PR Newswire in July 2026, projects the same broad category will grow "to reach USD 17.56 billion by 2031 from USD 5.09 billion in

2026, at a CAGR of 28.1%" (Source: prnewswire.com). The two forecasts differ in base-year figures, which is typical of market-research houses using different scope definitions and methodologies, but both point to a market compounding at 24% to 28% a year through the early 2030s, consistent with the multi-year rise in FDA-facing submissions.

Actual adoption inside pharmaceutical companies appears more measured than the market forecasts imply. A Tufts Center for the Study of Drug Development global survey of 302 organizations, fielded between May and August 2024, found that "36.9%" of respondents were "not yet using or implementing AI/ML" across clinical development activities, while "on average only 10.7% had fully implemented AI/ML" (Source: pubmed.ncbi.nlm.nih.gov). This gap between rapid FDA-facing submission growth and comparatively modest full implementation suggests companies are experimenting broadly and disclosing that experimentation in early-stage filings well before AI tools are deeply embedded in core development workflows.

Regulatory-affairs-specific survey data reinforces a similar picture of accelerating but incomplete adoption. A late-2025 RAPS and PwC global benchmarking survey of "more than 660 participants across 60 countries" found "45% of respondents investing in regulatory AI and 68% planning to invest in the next two years" (Source: raps.org) (Source: raps.org). A separate ArisGlobal-commissioned Censuswide survey of senior U.S. regulatory professionals, fielded in September 2024, found "almost half (48%) of respondents believe AI will transform routine regulatory work and considerably streamline processes" (Source: prnewswire.com).

Quantified efficiency claims from major consultancies add texture to the "why" behind rising AI-referencing submissions. McKinsey's analysis of clinical development found that "a 12-month reduction in the clinical development timeline can add more than $400 million in net present value" per program, and that AI/ML-driven site selection can compress recruitment timelines meaningfully (Source: mckinsey.com). Deloitte's analysis of generative AI in medical writing found that automation "can reduce medical writer effort by 20% to 30%, yielding a potential annual cost savings of $30 million on average" for a top-10 biopharmaceutical company (Source: deloitte.com), a workflow closely tied to the regulatory-authoring process that feeds directly into FDA submissions. Deloitte's broader 2026 Life Sciences Executive Outlook, based on a survey of "280 C-suite executives from biopharma and medtech companies" fielded in August and September 2025, found more than three-quarters expressing confidence in their own organizations' financial outlook even as they balance AI investment against regulatory complexity (Source: deloitte.com).

To put the submission counts in proportion, CDER's baseline intake is substantial: the center "receives about 1500 initial Investigational New Drug applications (INDs) per year" (Source: ovid.com), and it has "approved an average of 47 novel drugs per year over the last decade, reaching a high of 59 novel drug approvals in 2018 and a low of 22" (Source: raps.org). A Nature Reviews Drug Discovery analysis of 2025 approvals found the "5-year average down a touch, to 48 new drugs per year," still comfortably above "the historic average, of 36 new drugs per year since 1993" (Source: nature.com). Set against roughly 1,500 annual IND filings, the available public disclosures do not support comparing the cumulative 300-plus AI-submission figure with a single year of CDER intake. The reported 2022 figure of 170 submissions remains a minority share of that annual baseline, and the available data show AI-related submissions were concentrated overwhelmingly in the investigational rather than final-approval stage.

Case Studies and Real-World Examples

Insilico Medicine's rentosertib, also known as INS018_055 or ISM001-055, is among the most closely documented examples of an AI-originated drug advancing through the clinical and regulatory pipeline. Insilico announced that its Nature Medicine publication represented "the industry's first proof-of-concept clinical validation of AI-driven drug discovery," referring to the fact that both the drug's target, TNIK, and its molecular structure were generated using the company's generative AI platform (Source: insilico.com). The peer-reviewed publication describes the underlying trial as "the first phase 2a multicenter, double-blind, randomized, placebo-controlled trial testing the safety and efficacy of rentosertib" in idiopathic pulmonary fibrosis (Source: pubmed.ncbi.nlm.nih.gov). Insilico reported that patients on the highest studied dose showed a "mean change of +98.4 mL, compared to a mean decline of -20.3 mL in the placebo group" in a key lung-function measure (Source: insilico.com). The program has since advanced to a Phase 3 confirmatory trial registered on ClinicalTrials.gov as NCT07687459, sponsored by Insilico Medicine Hong Kong Limited (Source: clinicaltrials.gov), illustrating a full path from AI-driven discovery through an FDA-regulated Phase 3 program.

Exscientia offers a second, earlier example of AI-designed molecules reaching FDA-regulated human trials. In February 2023, its EXS4318 compound, in-licensed by Bristol Myers Squibb, became "the first immunology & inflammation candidate designed by Exscientia and its fourth molecule to enter the clinic" (Source: businesswire.com). By May 2023, Exscientia announced its sixth generative-AI-designed molecule to enter clinical development, disclosing that its partner "Sumitomo Pharma Co., Ltd. ('Sumitomo Pharma') plans to initiate a Phase 1 clinical study of DSP-2342 in the United States" (Source: businesswire.com), reflecting a repeatable pipeline of AI-designed candidates entering FDA-regulated IND-stage development.

Recursion Pharmaceuticals provides a third example, notable for the speed of its FDA clearance. The company announced that "the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug (IND) application for a Phase 1/2 clinical trial of REC-1245" (Source: ir.recursion.com) in October 2024, a molecule the company describes as originating from its AI-based maps of biology used to identify a first-in-class

RBM39 degrader target for biomarker-enriched solid tumors and lymphoma. GEN (Genetic Engineering & Biotechnology News) coverage of the clearance quoted Recursion's chief executive on the pace of the underlying discovery process, describing it as moving at "nearly twice the speed of the industry average" (Source: genengnews.com).

Iambic Therapeutics offers a fourth example. Its IAM1363, an AI-discovered HER2 inhibitor, was described by the company as the "first candidate from Iambic's AI-driven, physics-informed, discovery platform to reach Investigational New Drug (IND) submission" (Source: iambic.ai), an approach that pairs generative AI design with physics-based simulation rather than the purely data-driven models used by some peers, illustrating methodological diversity among AI-originated candidates now in FDA-regulated development.

Absci provides a fifth example, notable for being a generative-AI-designed biologic rather than a small molecule. Its ABS-101, described as the "first AI-designed biologic for IBD, beginning Phase 1 trial," is an anti-TL1A antibody for inflammatory bowel disease; Absci announced that the first participants were dosed in May 2025 (Source: globenewswire.com). Therapeutic monoclonal antibodies for in-vivo use are generally regulated by CDER, subject to FDA's stated product-jurisdiction exceptions (Source: fda.gov).

FDA's own Elsa rollout stands as a sixth, distinct case, this time of the agency using AI on the review side rather than sponsors using it in their filings. As detailed above, FDA launched Elsa agency-wide on June 2, 2025, and by its own account scaled staff generative AI usage "from just 1% in early 2025 to over 80% today" by May 2026 (Source: nextgov.com), a rare disclosed adoption curve for a federal regulator's internal AI tool.

FDA's Digital Health Advisory Committee, convened for the first time on November 20 and 21, 2024, provides a seventh case illustrating how the agency is institutionalizing external expert input specifically on generative AI. The committee "met on November 20-21, 2024, to discuss and provide advice on 'Total Product Lifecycle Considerations for Generative AI-Enabled Devices'" (Source: fda.gov), a meeting at which Commissioner Califf disclosed the comparative drug-versus-device submission figures discussed earlier in this report (Source: endpoints.news). A subsequent legal analysis of that meeting concluded it "highlights the potential need for additional regulatory controls and approaches" for generative AI-enabled products (Source: jdsupra.com), while the same analysis quoted Commissioner Califf explaining the agency's rationale for engaging with generative AI despite acknowledged risks, stating FDA must do so "not only to keep pace with the industries we regulate" but to serve patients directly (Source: jdsupra.com).

Implications and Future Directions

The trajectory documented across CDER's disclosed submission counts, from one filing a year in 2016 to over 800 by 2026, suggests the January 2025 draft guidance is unlikely to be FDA's last word on AI in drug development. The guidance itself is a draft, its 7-step credibility framework has not yet been finalized into binding guidance, and the two 2023 discussion papers remain open channels for stakeholder feedback that FDA has said will inform future rulemaking. Sponsors preparing IND, NDA, ANDA, or BLA submissions that rely on an AI or ML model for any function touching the nonclinical, clinical, postmarketing, or manufacturing stages should expect to apply the seven-step credibility assessment proactively, since ISPE's own comment letter, even while commending the framework's clarity, signals that industry groups are still negotiating its finer points with the agency (Source: ispewebassets.org).

Internally, the tension visible in FDA's own reporting between rapid generative AI adoption, reaching over 80% of staff by mid-2026 (Source: nextgov.com), and documented reliability concerns about Elsa's outputs (Source: engadget.com) is likely to remain a live governance question. FDA's insistence that Elsa use is voluntary and that the tool does not train on regulated-industry data are both structural safeguards worth monitoring as adoption climbs further and as the tool takes on more substantive review tasks.

For pharmaceutical and life-science organizations navigating this landscape, the practical challenge is less about whether to disclose AI use in a submission, since CDER's keyword-search methodology will likely surface it regardless, and more about building the documentation, validation evidence, and cross-functional governance the credibility framework expects before a submission is filed. This is squarely the kind of regulatory-technology integration work that life-science consultancies advise on. **IntuitionLabs**, a life-sciences and AI consultancy and an official Veeva Vault CRM X-Pages partner, positions its advisory practice around exactly this intersection, describing its consulting offering as providing "strategic guidance on digital transformation, AI adoption, and technology roadmapping" for pharmaceutical and life-science organizations (Source: intuitionlabs.ai), and describes the AI-enabled solutions it builds for regulated clients as offering "built-in compliance with FDA, EMA, and global regulations" (Source: intuitionlabs.ai). As FDA's credibility-assessment expectations mature from draft into final guidance, sponsors that treat documentation and context-of-use justification as a design requirement from the outset, rather than a retrofit before filing, are best positioned to avoid delays tied to AI-specific review questions.

CDER's cumulative AI-referencing submission figures and CDRH's public AI-enabled device list count different regulatory units, so their numerical difference does not show a relative level of AI adoption. FDA's current draft guidance addresses AI used to produce information or data intended to support regulatory decision-making for drugs and provides non-binding recommendations; if finalized, FDA states that the guidance would still not bind

FDA or the public (Source: fda.gov).

Frequently Asked Questions (FAQs)

How many FDA submissions use AI? CDER's own disclosures put the cumulative count of AI- or ML-referencing drug and biologic submissions at over 500 through 2023 (Source: medcentral.com) and over 800 by early 2026 (Source: nature.com), up from just one submission per year in 2016 and 2017 (Source: doi.org).

What is CDER's process for reviewing AI-enabled submissions? There is no separate review track; reviewers apply the same IND, NDA, ANDA, or BLA review process, but for submissions whose AI model outputs affect a regulatory decision, FDA's January 2025 draft guidance recommends sponsors apply a 7-step, context-of-use-specific credibility assessment framework, which PharmaVoice's reporting on the guidance noted still leaves "many are still left wanting more" clarity on implementation details (Source: pharmavoice.com).

Does FDA guidance cover AI used in drug discovery? No. The January 2025 draft guidance explicitly states it "does not address the use of AI models (1) in drug discovery or (2) when used for operational efficiencies" (Source: fda.gov), focusing instead on nonclinical, clinical, postmarketing, and manufacturing uses.

What is Elsa, and is it the same as an "AI submission"? No. Elsa is FDA's own internal generative AI tool for staff, launched June 2, 2025, whose debut BioSpace described as a "clunky launch of Elsa, an AI tool to increase efficiency, has sparked concern" among both staff and outside observers (Source: biospace.com); it is separate from sponsor-side AI use inside a submission, which is what CDER's submission counts track.

Which therapeutic areas use the most AI in FDA submissions? Oncology leads, accounting for roughly 27% of the 132 AI/ML submissions received in 2021, followed by psychiatry at 15% and gastroenterology at 12% (Source: raps.org).

How does this compare to AI-enabled medical devices? Devices vastly outnumber drug submissions on FDA's AI ledger. CDRH's public AI/ML-Enabled Medical Device List showed 1,524 authorized devices as of March 2026, with a peer-reviewed analysis finding "264 per year between 2023 and 2025, with 331 authorizations recorded in 2025" alone (Source: doi.org), compared with roughly 500 to 800 cumulative AI-referencing drug and biologic submissions to CDER.

Conclusion

FDA's disclosures show substantial growth in AI- or ML-referencing submissions: from one per year in 2016 and 2017, to 132 in 2021, to more than 500 CDER submissions from 2016 through 2023, and to more than 800 cumulative CDER submissions by early 2026. The January 2025 AI guidance remains Draft Level 1 guidance, is not for implementation, and contains nonbinding recommendations. Its risk-based, seven-step credibility assessment framework may be used to establish and evaluate an AI model's credibility for a particular context of use. AI-originated molecules and biologics are advancing through FDA-regulated clinical trials. FDA's public AI-enabled-device authorization list and CDER's AI-referencing submission figures provide complementary context, but they are not directly comparable because they count different regulatory units.

Tags: fda ai submissions, cder artificial intelligence, ai drug development, fda ai guidance, ai regulatory submissions, fda elsa ai tool, ai drug discovery, machine learning fda, ai medical devices fda, cder ai review process

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