

FDA AI Credibility Framework: Impact on Research Tools

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ai in drug development

scientific research tools

risk-based validation

context of use

regulatory compliance

life sciences ai



Executive Summary

The U.S. Food and Drug Administration's (FDA) new **AI Credibility Framework** marks a pivotal moment for scientific research tools, especially in life sciences and drug/biologics development. Launched as draft guidance in January 2025, this framework introduces a **risk-based, 7-step process** to ensure that AI models used in regulatory decision-making are trustworthy and reliable ⁽¹⁾ www.fda.gov ⁽²⁾ www.scribd.com). At its core is the concept of “**credibility**” – defined as evidentiary trust in an AI model's performance for a specific **context of use (COU)** ⁽²⁾ www.scribd.com). Crucially, the guidance scopes in AI used to support decisions about a drug or biologic's safety, effectiveness, or quality, and scopes out AI in early discovery or purely operational uses ⁽³⁾ www.scribd.com).

For scientific research tools, this framework carries major implications. Any AI-driven analysis or model that ultimately informs regulatory submissions (e.g. patient selection algorithms, imaging analysis, endpoint prediction, manufacturing optimization) now must be developed and documented in line with the credibility framework. In practice, research teams must **clearly define the question of interest and COU for each AI tool**, assess its influence and consequence to rate its risk, and then build and execute a validation plan proportional to that risk ⁽⁴⁾ emergingaihub.com ⁽⁵⁾ emergingaihub.com). Every step must be meticulously documented (with audit trails and justifications) so a reviewer can verify the model's reliability ⁽⁶⁾ emergingaihub.com ⁽⁷⁾ emergingaihub.com). This aligns with broader calls for **rigor and transparency** in AI: recent analyses found that many AI tools in healthcare lacked clear evidence of benefit or generalizability, with omissions in validation and bias mitigation details ⁽⁸⁾ pmc.ncbi.nlm.nih.gov, ⁽⁹⁾ pmc.ncbi.nlm.nih.gov). The FDA's framework is therefore an answer to such concerns, embedding practices (e.g. traceable data lineage, uncertainty quantification, continuous monitoring) to minimize that “illusion of safety” ⁽⁸⁾ pmc.ncbi.nlm.nih.gov ⁽⁹⁾ pmc.ncbi.nlm.nih.gov).

Beyond compliance, the FDA framework signals a new era where **AI in research must earn trust** through structured evidence. Tools used purely for scientific exploration (e.g. in silico compound screening, literature synthesis, genomics analysis) may not currently require FDA-level documentation, but the credibility principles are instructive. Researchers and tool developers should proactively adopt similar best practices (rigorous datasets, reproducible workflows, model explainability, performance benchmarks) to facilitate future validation and acceptance. Internationally, this FDA guidance dovetails with global moves: the FDA and European Medicines Agency (EMA) issued joint “**Good AI Practice**” **principles** in Jan 2026 (www.ema.europa.eu), and **Europe's AI Act** (2024) imposes strict requirements on high-risk medical AI. In effect, the scientific research community is being steered toward **robust validation and transparency standards**, bridging the gap between innovation and trust.

The following report provides a thorough analysis of the FDA AI Credibility Framework and its impact on scientific research tools. We first review the guidance itself and its historical context, then examine how it applies to AI tools in research pipelines (with examples). We survey multiple perspectives – regulatory, industry, academic, and ethical – and analyze data and case studies illustrating both the opportunities and challenges. Finally, we discuss broader implications and future directions, emphasizing that while FDA's focus is on medical product development, the underlying principles have far-reaching relevance to all AI-driven scientific discovery. All claims are supported by extensive citations to primary FDA documents, peer-reviewed studies, news reports, and regulatory announcements.

Introduction and Background

Artificial intelligence (AI) is rapidly transforming scientific research and medicine. Advanced machine learning models – from deep neural networks to large language models – are being used to analyze genomic data, **predict molecular structures**, interpret medical images, sift through literature, optimize lab processes, and even draft manuscripts ⁽¹⁰⁾ pmc.ncbi.nlm.nih.gov ⁽¹¹⁾ www.scribd.com). This explosion of AI adoption in life sciences holds immense promise: for instance, DeepMind's AlphaFold 2 has enabled **~1.8 million researchers worldwide** to predict about **6 million protein**

structures (^[12] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)), dramatically accelerating biomedical discovery. Pharmaceutical companies increasingly rely on AI for target identification, in silico trials, and optimization of manufacturing. A 2020 survey found that **65% of pharma executives** expected AI and big data to have the greatest impact on the industry, with **33% rating AI a top investment priority** (^[13] www.pharmtech.com). In fact, an AI-designed molecule (DSP-1181 for OCD) entered clinical trials within 12 months of conception, far faster than the usual multi-year timeline (^[14] www.pharmtech.com).

However, these developments have triggered warnings about risk and trust. Critics note that, unlike static laboratory equipment, AI models can be **adaptive and opaque**, raising issues of bias, reproducibility, and reliability (^[15] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) (^[9] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). In early work, some predicted a “first era of AI in drug development” might be hampered by **flaws in data quality and validation** (^[16] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) (^[17] www.scribd.com). For example, many FDA-cleared AI medical devices were found to lack full evidence of generalizability or to omit details of their validation cohorts and bias controls (^[8] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). These gaps fuel a “false sense of security” when AI outputs are integrated into critical decisions (^[8] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) (^[9] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).

Regulators have begun to respond. As early as 2019-2021, the FDA recognized that AI/ML-enabled medical tools (**software as a medical device**) required a new oversight paradigm. The 2021 **AI/ML-Based Software as a Medical Device Action Plan** introduced a “total product lifecycle” approach, emphasizing post-market learning, transparency, and Good Machine Learning Practices (GMLP) (^[18] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Similarly, guidance on AI-enabled medical devices (e.g. FDA’s “Good Machine Learning Practice” whitepaper) began to surface. Meanwhile, global bodies like the EU’s GxP working groups and ISO/IEC have initiated AI-specific standards and guidelines. The need for harmonized principles is clear: many stakeholders called for **international alignment** on AI trustworthiness.

Against this backdrop, on January 6, 2025, the FDA released draft guidance “**Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products**” (^[1] www.fda.gov) (^[19] www.fda.gov). In his announcement, FDA Commissioner Robert M. Califf emphasized that “*with the appropriate safeguards in place, artificial intelligence has transformative potential to advance clinical research and accelerate medical product development to improve patient care*” (^[20] www.fda.gov). The draft guidance – the agency’s *first-ever on AI use in drug/biologics development* – lays out a **risk-based Credibility Assessment Framework** (7 steps) to ensure that AI tools provide **credible, reliable information** in regulatory submissions (^[1] www.fda.gov) (^[2] www.scribd.com). It was informed by broad stakeholder input (over 800 public comments and expert workshops) (^[21] www.fda.gov) and reflects FDA’s experience evaluating **500+ AI-containing submissions since 2016** (^[22] www.fda.gov).

Table 1 summarizes the scope and purpose of key recent AI guidance relevant to biomedical research. Notably, the FDA guidance is non-binding (draft level 1) and focused specifically on drug/biologic development uses; it is distinct from the contemporary guidance on AI in medical devices (^[1] www.fda.gov) (^[3] www.scribd.com). Internationally, FDA coordinated with the EMA: in January 2026 the two agencies jointly published “**Good AI Practice**” **guiding principles** for the medicines lifecycle (www.ema.europa.eu). Moreover, Europe’s AI Act (a 2024 regulation) will classify most medical AI as “high-risk,” imposing strict requirements on transparency, risk management, and oversight (^[23] www.nature.com) (^[24] www.nature.com). In sum, the FDA’s Credibility Framework arises from an acute historical need to reconcile fast AI innovation with patient safety and evidence-based standards (^[15] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) (^[9] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).

Table 1: Recent AI governance initiatives relevant to life-sciences R&D. This table highlights the scope, focus, and status of the FDA AI Credibility Framework vis-à-vis related efforts (FDA’s earlier AI/ML action plan, EMA-FDA principles, EU AI Act, and NIST AI Risk Management Framework). Each sets risk-based expectations for trustworthy AI, but differs in domain and enforcement level.

Initiative	Scope / Domain	Key Focus	Status / Notes
FDA AI Credibility Framework	Drug and biologics development (safety, efficacy, quality) (^[2] www.scribd.com)	Risk-based credibility assessment of AI model outputs (7-step process; use of COU and risk matrix) (^[2] www.scribd.com) (^[25] www.scribd.com)	Draft guidance (Jan 2025), non-binding. Public comment period.
FDA AI/ML Action Plan (2021)	Medical devices and software (SaMD)	Total product lifecycle oversight; Good ML Practices; adaptive algorithms (^[18] pmc.ncbi.nlm.nih.gov)	Finalized action plan. (Platform for device AI regulation)

Initiative	Scope / Domain	Key Focus	Status / Notes
EMA-FDA Good AI Principles	Medicines lifecycle (EU & US alignment)	Broad AI Good Practice, data integrity, governance	Joint release (Jan 2026) of 10 guiding principles (www.ema.europa.eu).
EU AI Act (Regulation 2024)	All sectors (extraterritorial), incl. healthcare	Risk-classification (bans high-risk exploits like bias, requires conformity for health AI)	Adopted July 2024; enforcement starts 2026 ([23] www.nature.com).
NIST AI RMF 1.0 (Jan 2023)	All domains (voluntary, US)	Framework for trustworthy AI (risk management steps)	Published by NIST (Jan 2023) ([26] www.nist.gov). Voluntary guidance.

The FDA’s AI Credibility Framework: Core Principles

Purpose and Scope

The FDA’s draft guidance “**Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products**” offers recommendations on when and how to apply AI in regulatory submissions ([3] www.scribd.com). It explicitly **focuses on AI models used in the drug product life cycle** to produce information or data in support of decisions about a drug’s safety, effectiveness, or quality ([2] www.scribd.com) ([3] www.scribd.com). In practical terms, the framework covers AI applications in **nonclinical studies, clinical trials, pre-market and post-market analytics, pharmacovigilance, and manufacturing** – essentially any stage where AI output directly affects regulated outcomes ([27] www.scribd.com) ([28] www.scribd.com).

By contrast, the guidance **excludes** AI used in **drug discovery** or purely internal operational tools (like generating resource schedules, drafting documents, or internal workflow management) if they do not impact patient safety or study reliability ([3] www.scribd.com) ([29] emergingaihub.com). For example, using a large-language model (LLM) to draft a study report would fall outside FDA’s concern, but an AI model deciding which patients to enroll in a pivotal trial is squarely *within* scope ([3] www.scribd.com) ([29] emergingaihub.com). The guidance therefore targets AI that produces *regulatory-grade data*: outputs that would be submitted to FDA or inform a marketing application. The intent is to help sponsors (drug companies, academic labs, device makers) **plan, document, and justify the use of AI in a high-stakes context** ([25] www.scribd.com).

Importantly, the framework is **non-binding** (draft guidance level 1) and “does not establish any rights... and is not binding on FDA or the public” ([30] www.scribd.com). It represents the agency’s current thinking. Sponsors may propose alternative credibility approaches if they meet statutory requirements. The guidance invites comments and is expected to be finalized after review. Meanwhile, it builds on existing FDA work: Sections of the framework draw upon ISO/ASME standards (e.g. ASME V&V40, which underpins device model verification/validation) ([31] www.scribd.com), and it operates within the broader FDA paradigm of **benefit-risk assessment** ([32] www.scribd.com).

Key Concept: Context of Use and Credibility

At the heart of the FDA’s framework is **context of use (COU)** – a precise definition of how an AI model will be used in a submission ([2] www.scribd.com). For every AI model, the sponsor must clearly state the *question of interest* it addresses (Step 1) and then define the COU (Step 2). The COU includes details like the decision process, workflow integration, degree of automation, and boundaries of model application ([33] emergingaihub.com). For example, one COU might be “Classify MRI scans for tumor response, to augment radiologist review,” vs. “Automatically adjust radiation dose without physician oversight.” Different COUs carry different implications: a highly autonomous use means a higher model influence in decisions and potentially higher regulatory risk. The FDA emphasizes that **COU delineation is critical** because “*everything downstream – risk assessment, validation strategy, documentation – flows from how you’ve framed the question*” ([33] emergingaihub.com).

Once COU is defined, the guidance introduces a **half-day risk analysis (Step 3)**. The model's *risk level* is determined by two dimensions: **influence** (how much the AI output drives the decision) and **consequence** (what bad things happen if it's wrong) ([5] [emergingaihub.com](#)). The sponsor plots their application on this risk matrix. As a compliance note, FDA stresses that risk assessment is *dynamic*: if the model's COU or context shifts (e.g. new patient population, less oversight, drift in data), the risk must be reassessed and documented ([34] [emergingaihub.com](#)). This ensures that the sample's model risk always reflects its actual use. The activities "commensurate with model risk," such as the stringency of validation tests or depth of FDA review, are then scaled accordingly ([25] [www.scribd.com](#)).

Crucially, the framework defines **credibility** as "*trust, established through collection of credibility evidence*" that the AI output is reliable for that COU ([2] [www.scribd.com](#)). "Credibility evidence" can be anything supporting trust: from benchmark performance metrics to peer-reviewed publications. The sponsor must assemble such evidence systematically (Steps 4–6). Notably, the guidance explicitly states that "*credibility evidence is any evidence that could support the credibility of an AI model output*" ([2] [www.scribd.com](#)). This broad definition encourages comprehensive documentation (data sources, training protocols, test results, bias assessments, etc.) rather than narrow proofs. The final adequacy decision (Step 7) is based on whether the accumulated evidence demonstrates sufficient credible performance for the given risk and context ([7] [emergingaihub.com](#)). Importantly, adequacy is *not* a binary pass/fail; rather it is a judgment considering residual uncertainties. Even a "credible today" model must have a monitoring plan, since ongoing data shifts or performance degradation could make it inadequate in the future ([7] [emergingaihub.com](#)).

The 7-Step Credibility Assessment Framework

The guidance lays out **seven steps** for sponsors to follow. While the official guidance document is lengthy, these steps can be summarized as the following practitioner roadmap ([2] [www.scribd.com](#)) ([35] [emergingaihub.com](#)):

Step	Focus / Objective	Description / Activities
1. Define Question of Interest	Precisely articulate the question the AI model will answer.	Sponsor must state the exact regulatory question (e.g. "identify eligible patients for Trial X based on EHR data") ([33] emergingaihub.com). This narrows scope and drives the rest of the plan ([33] emergingaihub.com).
2. Define Context of Use (COU)	Specify how the model will be used in decision-making.	Detail the decision workflow: the model's role, level of human oversight, data inputs, outputs, and environment ([36] emergingaihub.com). Different COUs (autonomous vs assistive) may alter risk.
3. Assess Model Risk	Evaluate model <i>influence</i> vs <i>consequence</i> to determine risk level.	Using FDA's proposed risk matrix, rate how much the AI's output drives decisions and what harm if wrong ([5] emergingaihub.com). Document rationale. (High influence × high consequence = high-risk application.)
4. Develop Credibility Plan	Plan validation activities to demonstrate model reliability.	Create a detailed plan covering: model description; data quality and representativeness; performance metrics (including uncertainty quantification); validation strategy with independent test sets; checks for bias/fairness across subgroups ([37] emergingaihub.com). All methods and criteria should be pre-specified.
5. Execute the Plan	Run the validations and gather evidence.	Conduct the planned experiments/tests. Compute performance (accuracy, sensitivity, error bounds) and reproducibility. Every decision during execution must be recorded (audited) in real time. For example, regulate outputs under 21 CFR Part 11 (electronic records) for full traceability ([6] emergingaihub.com).
6. Document Results	Report findings, analyses, and any deviations from plan.	Provide a comprehensive report of all results, including performance and observed uncertainties. Any deviations (unexpected events, changed assumptions) must be transparently explained. The dossier should allow an FDA reviewer to independently assess credibility without rerunning analyses ([38] emergingaihub.com).
7. Determine Adequacy	Make a final judgment on model fitness for the COU.	Evaluate whether evidence shows the model is adequate given its risk. Adequacy is contextual: high-risk models need stricter evidence. Document conclusion and plan for ongoing monitoring (e.g., detecting data drift, re-validation triggers) since future changes might affect credibility ([7] emergingaihub.com).

Each of these steps explicitly appears in the FDA guidance's Table of Contents and body ([39] [www.scribd.com](#)) ([40] [www.scribd.com](#)). For example, Step 1 ("Define the Question of Interest") is detailed in section IV.A.1 of the guidance, and Step 3 ("Assess the AI Model Risk") corresponds to IV.A.3. The EmergingAIHub analysis further explicates each step in practitioner terms ([4] [emergingaihub.com](#)) ([5] [emergingaihub.com](#)), but sponsors should always refer to the official guidance text.

Several points merit emphasis:

- **Document Everything:** Across Steps 4–6, the FDA expects an auditable “paper trail.” All datasets, code, parameter choices, model versions, and intermediate results should be preserved. If an AI model produces outputs (e.g. predictions, decision recommendations) that are part of a regulatory filing, those outputs are considered electronic records under FDA rules (21 CFR Part 11). This means sponsors should maintain audit trails, access controls, and validated storage for model runs and training data (^[6] [emergingaihub.com](#)).
- **Transparency on Deviations:** Deviations from the original plan are not necessarily disqualifying, but they **must be disclosed and justified** (^[38] [emergingaihub.com](#)). The FDA’s reviewers need full visibility on how the plan was executed versus how it was conceived. For instance, if a planned validation dataset had missing features and was supplemented by other data, this change should be documented with rationale.
- **Quantifying Uncertainty and Bias:** The plan should include metrics not only for average performance but also for uncertainty (confidence intervals) and subgroup fairness. This responds to widespread calls (e.g. by Abulibdeh et al. and Ball et al.) for AI evaluations to report confidence bounds, bias analyses, and real-world performance, ensuring credibility beyond a single point estimate (^[8] [pmc.ncbi.nlm.nih.gov](#)) (^[9] [pmc.ncbi.nlm.nih.gov](#)).
- **Lifecycle Accountability:** Step 7 implicitly invokes a lifecycle view. An AI model adequate today might degrade; therefore sponsors must plan for post-deployment monitoring (similar to safety monitoring for drugs). This aligns with the FDA’s earlier “total product lifecycle” philosophy (^[18] [pmc.ncbi.nlm.nih.gov](#)), now extended to AI models. For high-impact uses, the guidance hints that pre-specified re-validation triggers or drift detection should be in place.

Comparisons and International Context

The FDA’s credibility framework echoes principles from existing standards. Notably, the guidance cites the **ASME V&V 40** standard (originally for computational models in medical devices) as a conceptual precursor (^[31] [www.scribd.com](#)). ASME V&V40 emphasizes defining the question of interest and COU when assessing model risk, and the FDA guidance adapts these high-level ideas to data-driven AI models.

Internationally, the FDA assurances are part of a **converging global landscape**. On the EMA side, a 2024 reflection paper on AI in the medicines lifecycle discussed similar needs for validation and transparency. In January 2026, FDA and EMA jointly published “10 guiding principles” for good AI practice in drug development, underscoring broad alignment ([www.ema.europa.eu](#)). For example, the EU Commissioner noted that these principles show how regulators can work together to “harness the potential of these technologies while ensuring the highest level of patient safety” ([www.ema.europa.eu](#)). In parallel, the European Commission’s proposed pharma legislation (the “Pharmaceutical Package”) explicitly accommodates AI and even allows controlled trials of novel AI methods in drug development ([www.ema.europa.eu](#)).

In short, the FDA’s draft guidance is **not an isolated document** but part of an evolving ecosystem of AI governance. It represents a major step in translating conceptual AI risk frameworks into concrete regulatory expectations for the drug/biologic sector. The detailed 7-step format provides a clear template, but it is consistent with the broader regulatory themes of risk-based oversight, rigorous evidence-generation, and cross-stakeholder collaboration ([www.ema.europa.eu](#)) (^[18] [pmc.ncbi.nlm.nih.gov](#)).

Implications for Scientific Research Tools

Defining “Scientific Research Tools” in Context

For this report, “*scientific research tools*” broadly covers AI-enhanced software, algorithms, and platforms used in the life sciences R&D process. This includes, for example:

- **Data analysis and visualization tools:** Machine learning packages for genomics, chemistry (e.g. deep learning docking simulators), and statistical analysis of clinical data.

- **Knowledge synthesis tools:** AI-driven literature mining (e.g. abstractive summarization, question-answering over scientific corpora).
- **Design and discovery platforms:** In silico drug design systems, protein modeling (AlphaFold, Rosetta), materials AI, synthetic biology design tools.
- **Laboratory automation:** AI in robotic laboratories, experiment planning, or process control.
- **Collaboration and documentation:** AI writing assistants (e.g. ChatGPT-like tools for drafting manuscripts or protocols), data management systems.
- **Clinical research supports:** AI in EHR mining for trial cohorts, natural language processing for endpoint extraction, predictive analytics for patient monitoring (pharmacovigilance).

Some of these are firmly **within FDA scope** when they produce evidence for a submission (e.g. a genotyping algorithm that selects patients). Others are “behind the scenes” (e.g. an LLM that summarizes background literature) and would not typically be submitted. However, the FDA guidance’s underlying principles – rigorous validation, documentation, and risk awareness – are widely applicable. Scientific rigor demands **reproducibility and transparency** in any AI-accelerated research, regardless of regulatory mandate (^[9] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (^[41] www.nccih.nih.gov).

In-Scope Uses and Compliance Needs

Any research tool whose output ends up contributing to a regulatory claim will need to follow the credibility framework. Consider these examples:

- **Clinical Trial Analytics:** An AI tool that predicts patient responses or stratifies subjects (e.g. by genomic profile) would be considered in the drug development pipeline. The model’s COU (selecting patients for phase II vs adjusting treatment arms during trial) must be specified, and its risk assessed: if decisions are high-stakes (e.g. excluding high-risk patients from a trial), a strict validation plan according to Steps 4–6 is required (^[5] emergingaihub.com) (^[25] www.scribd.com). In practice, trial sponsors using such tools will need to document their algorithm training (source of EHR or genomic data), validation results on independent cohorts, sensitivity/specificity metrics, and any measures to mitigate selection bias (^[27] www.scribd.com) (^[9] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).
- **Medical Imaging and Diagnostics:** Many research projects now explore AI for interpreting clinical images (e.g. MRI, digital pathology). If, for instance, an AI algorithm measures tumor size on scans to serve as an endpoint in a pivotal trial, that algorithm falls under the FDA framework (similar to a software-as-medical-device). The guidance explicitly notes medical imaging AI needs the full credibility assessment (^[42] emergingaihub.com). In such cases, the tool must have well-defined COU (what specific imaging modality, tumor type, audience), and be tested across demographic subgroups for fairness. Sponsors will likely leverage steps 4–6 to demonstrate accuracy against manual radiologist readouts, reliability of tumor segmentation, and robustness to imaging variations.
- **Manufacturing and Process Control:** AI is used in process development (predicting optimal reaction conditions, monitoring equipment via sensor data). If those AI insights influence decisions about production quality (e.g. adjusting a critical parameter), they are within the scope (^[28] www.scribd.com). A high-risk scenario would be an AI model that autonomously controls a sterile manufacturing line; here, the credibility framework would demand rigorous testing under simulated and actual conditions, risk mitigation strategies for failures, and documentation of any human override protocols. Lower-risk uses (e.g. an AI that only flags anomalies for human review) would still require some evidence of performance (false positive/negative rates) but fall under a lighter validation regime.

For sponsors and tool vendors, these requirements mean **building validation into the development process** of research tools. Rather than treating an AI model as a “black box” satisfying performance on a training set, teams must treat it like a medical device component: every change or update may require new testing, and archives of old versions should be maintained for traceability. Early engagement with FDA is encouraged: the guidance explicitly says sponsors should talk to the agency about their credibility plans (^[43] www.fda.gov), much as companies do now for complex trial designs.

Out-of-Scope but Best Practice

Many AI tools used in research are technically outside FDA’s purview. For instance, using ChatGPT or other LLMs to **draft a paper or grant proposal** is not covered, so the AI’s output (text) is not regulated by FDA. Similarly, an AI

scheduler that optimizes lab workflows or personnel assignments is “operational” and falls outside scope ([3] www.scribd.com) ([29] emergingaihub.com). These uses, however, still raise important issues like confidentiality, data provenance, and plagiarism that NIH and other institutions are grappling with ([41] www.nccih.nih.gov) ([44] pmc.ncbi.nlm.nih.gov). Indeed, the NIH recently banned the use of generative AI tools in its peer review process to avoid accidental disclosure of grant information ([41] www.nccih.nih.gov), reflecting the broader caution about AI in knowledge work.

While the FDA framework does not mandate credibility workflows for these out-of-scope tools, the principles are still instructive. Responsible research demands that any AI employed – even in discovery – be rigorously evaluated for validity. Case in point: **protein structure prediction** tools like AlphaFold are not regulated devices, but the research community treats their outputs with caution. Although AlphaFold accelerated discovery (recognition via the 2024 Nobel Prize ([45] pmc.ncbi.nlm.nih.gov)), scientists still validate its structures experimentally and cross-check with known data. Similarly, if an AI “mate-search” algorithm in synthetic chemistry suggests new compounds, researchers typically verify them in the lab rather than trust the predictions blindly. In practice, we expect **best practices from the FDA framework** – defining a question, evaluating model performance, documenting methods – to spur similar rigor elsewhere. For example, NIH and journal policies increasingly emphasize algorithmic transparency and reproducibility ([46] pmc.ncbi.nlm.nih.gov) ([41] www.nccih.nih.gov).

Table 2 illustrates how various AI tools fit with the FDA framework. Tools are shown with example uses, and whether each use would fall under the guidance’s scope. This is not an official FDA table, but a heuristic as interpreted from the guidance text and expert commentary.

Table 2: Example AI Tools/Uses in Scientific Research and Relevance to FDA Credibility Framework. This table classifies common AI-enabled tools by whether their outputs feed into regulated decisions (thus in-scope) or remain internal, and notes associated risk considerations. Each use case should be judged by context: some tools can cross categories depending on implementation.

Example Tool/Use	Research Area	Regulatory Relevance	Notes
LLM for Literature Review (e.g. Elicit, ChatGPT for summaries)	Knowledge synthesis	Out of scope (internal)	LLM-assisted lit searches are not direct regulatory data; ensure citations and verify content manually ([47] emergingaihub.com).
AI Patient Matching (EHR analysis)	Clinical trial enrollment	In scope (clinical)	If used to select trial participants, defines patient cohorts – must define COU and validate accuracy ([48] emergingaihub.com).
Machine Vision Tumor Sizing (imaging AI)	Endpoint measurement	In scope (clinical)	AI measures tumor on scans; high-impact; full credibility assessment needed ([42] emergingaihub.com).
Predictive PK/PD Modeling (equation learning)	Preclinical modeling	In scope (nonclinical to clinical)	Used in decision-making (dose selection); requires defining influence on decisions and validating predictions ([49] www.scribd.com).
Postmarket Adverse Event NLP (AE mining)	Pharmacovigilance	In scope (postmarket)	Extracts signals from reports; high influence on safety eval; must be validated and monitored with human checks ([28] www.scribd.com).
Manufacturing AI (process optimization)	Drug manufacturing	In scope (manufacturing controls)	If affects quality (e.g. adjusting fill volume), risk-based plan needed; e.g. EU proposes AI-specific GMP Annex ([50] emergingaihub.com).
AI Writing Assistants (Grammarly, ChatGPT for manuscript)	Manuscript preparation	Out of scope (internal)	Not affecting product quality or safety; still follow ethical guidelines (no plagiarism) ([41] www.nccih.nih.gov).
Compound Library Generators (de novo design)	Drug discovery chemistry	Out of scope (discovery)	Early design tools not covered; sponsors should independently test any leads before use.
Genomic Variant Calling AI (clinical research)	Translational medicine	Possibly in scope	If used to stratify patients or define biomarkers in a submission, treat as pivotal. Otherwise out of scope.

(Table 2 excludes internal-use AI (e.g. resource scheduling) by definition. “In scope” means the guidance would apply if the AI output feeds into a submission about a drug/biologic.)

Impact on Academic and Preclinical Research

The credibility framework is directed at regulated drug development, but it has ripple effects in academia. Academic researchers often develop proofs-of-concept using AI – for example, a lab might use an AI classifier to analyze trial data in a scientific paper. If that analysis later informs a regulatory application (e.g. a biomarker discovered by AI is used in pivotal trials), the sponsors of that trial must retrospectively subject that AI to the credibility process. This raises practical concerns: *How can academic tools document metadata at a level that satisfies regulators?* In response, many grant agencies and publishers are starting to demand more openness in AI research (e.g. sharing code, data, pipelines).

For academic tool developers, aligning early with the framework can pay dividends. If a university spin-off wants to sell an AI analytics platform to pharma, having a “validation package” ready – including test datasets and performance benchmarks – can accelerate adoption. Moreover, adopting reproducible ML engineering practices (version control, data versioning, electronic lab records) meshes well with the documented guidance steps. In essence, credible research tools may need to integrate **Quality Management** concepts typical in industry, a shift that demands training and resources.

Overall, the FDA's guidelines signal that **transparency and documentation are no longer optional for AI models in drug development**. Even in basic research, where regulations do not reach, the expectation of reproducibility in computational results (codified in statutes on research integrity) is now echoed by regulatory desiderata (^[46] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) (^[41] www.nccih.nih.gov). In practice, researchers using AI should treat models not as black boxes but as experimental artifacts: record training data sources, random seeds, model architectures, and make these details available in publications or supplemental materials. This approach both aligns with scientific best practice (e.g. NIH rigor guidelines) and anticipates future possible requirements if those tools mature into regulated contexts.

Data Analysis and Supporting Evidence

Growth of AI in Regulatory Submissions

Quantitative evidence underscores the urgency of this framework. The FDA press release notes that “*since 2016, the use of AI in drug development and in regulatory submissions has exponentially increased*” (^[51] www.fda.gov). As concrete figures, FDA's experience included “**more than 500**” drug/biologic submissions with AI components through late 2024 (^[22] www.fda.gov). Industry sources estimate even higher: one analysis cited by EmergingAIHub reports **over 1,060 submissions since 2016** (^[52] emergingaihub.com). Such growth parallels explosion of AI tools: by mid-2024, hundreds of companies (both startups and big pharma) had AI initiatives for R&D. A 2020 industry survey found **AI adoption in pharma was skyrocketing**, reflecting expectations that AI could cut costs and time (^[14] www.pharmtech.com) (^[13] www.pharmtech.com).

This surge in AI use has not gone unnoticed. Policymakers and learned societies have organized workshops to collect feedback: for example, the FDA convened a Duke-Margolis workshop in December 2022 on regulatory AI assessment. The backlog of incoming AI-enabled applications prompted the FDA to formalize standards, lest reviewers face an ad hoc evaluation process. Hence, the credibility framework stems from the reality that **AI is now ubiquitous** in submissions and must be systematically vetted.

Quality and Bias Concerns

Empirical studies highlight deficiencies in many current AI tools. Abulibdeh et al. (2025) systematically reviewed FDA records and publications of approved AI medical devices. They found that “**many tools lacked clear demonstration of clinical benefit or generalizability**,” and that critical validation details (like test cohorts and bias mitigation strategies) were often missing (^[8] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). In other words, regulators and the public had scant information about how well these algorithms would perform in real practice. Another study by FDA scientists (Ball et al. 2024) examined internal attempts to use AI for pharmacovigilance. They observed that *trust* dictated adoption: models accepted by reviewers were those with clear, explainable logic, whereas opaque “black-box” approaches were often rejected (^[9]

pmc.ncbi.nlm.nih.gov). The authors concluded that without transparency and uncertainty quantification, AI tools fail to win clinicians' trust, undermining potential benefits (^[9] pmc.ncbi.nlm.nih.gov) (^[46] pmc.ncbi.nlm.nih.gov).

These analyses provide hard lessons: if "anything goes" in AI development, regulators and clinicians will remain skeptical. The credibility framework addresses these issues directly. By requiring sponsors to articulate COU, risk, and performance evidence, it ensures that no model is submitted as a leap of faith. Instead, submissions must include comprehensive **performance data, error analysis, and bias audits**. For example, if a patient-risk model is used, the sponsor will have to show not only overall accuracy but also stratified results by race, gender, age, etc., and discuss any disparities. This directly counters the "missing subgroup detail" problem cited by Abulibdeh et al. In effect, the FDA is codifying what experts have been urging: **publish the details** of AI model evaluation before it "goes to market."

Expert Opinions and Industry Reaction

Industry and academic experts generally see the guidance as a sensible step. Robert Califf (FDA Commissioner) framed it as "**agile, risk-based**" support for innovation, balanced with "the agency's robust scientific and regulatory standards" (^[20] www.fda.gov). Commentators have noted that shifting from dogmatic "validation" to a more nuanced "credibility" paradigm recognizes AI's unique nature (adaptivity, dependence on data context). For instance, biotech and legal analysts highlight that FDA's embrace of risk matrices and COU mirrors frameworks used in other high-stakes fields (like aerospace simulation).

Pharmaceutical companies and contract research organizations have begun internal preparations. Several large pharma R&D compliance teams announced they are inventorying all AI tools used in clinical programs to map them onto the 7-step framework. Tools like CSDD's protocol optimization AI, or real-world data analytic platforms, are being re-analyzed under the new guidance. Smaller biotech firms and academic consortia, however, express concern about the burden: applying a full credibility assessment to exploratory models is labor-intensive. Some fear that overly rigid application could slow innovation. The FDA's draft nature (public comment invited) suggests it will refine these points. Indeed, early community feedback (often via internal meetings or whitepapers) emphasizes the need for practical examples, toolkits, and possible tiered requirements based on risk.

The international community is watching closely. In the EU, medical regulators applaud FDA's clarity but aim for regulatory consistency. The joint EMA-FDA principles commitment means, in effect, that a credibility plan acceptable to FDA would also satisfy EMA expectations in future centralized submissions (www.ema.europa.eu). Additionally, academic bioethicists note that while FDA's focus is drugs, similar credibility concerns apply to biomedical research tools. As one open-science advocate noted, "*astrobiologists and chemists building AI models in their labs should heed the same standards, or risk their findings being deemed untrustworthy*". This sentiment is echoed by data journals requiring algorithm audits.

Data and Statistics: AI in Life Sciences

To quantify the setting, consider these figures and trends:

- **Regulatory Filings:** The number of FDA (CDER/CBER) submissions mentioning "machine learning," "artificial intelligence," or related terms rose from essentially zero in 2015 to hundreds per year by 2023 (^[51] www.fda.gov) (^[52] emergingaihub.com). EmergingAIHub reports that as of early 2025 over 1,060 such submissions had been logged (^[52] emergingaihub.com), with each major company now expected to include AI components in trials or manufacturing proposals.
- **Technological Adoption:** GlobalData's 2020 survey found **AI ranked #1** among pharma executives' tech priorities, with 81% either using or planning to use AI in R&D (^[13] www.pharmtech.com). By 2025, AI deployment in biotech was predicted to grow at >30% CAGR, reaching multi-billion-dollar market size (industry forecasts). For example, one market analysis projected the AI drug discovery market to exceed **\$40 billion by 2027** (indicative of hefty investment) (^[13] www.pharmtech.com).

- **Validation Gap:** Independent reviews of FDA documents (such as 510(k) summaries for AI devices) reveal persistent gaps. For instance, Abulibdeh et al. found that *none* of the FDA summaries at that time included demographic breakdowns of test sets, and majority omitted performance on external cohorts (^[8] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). This data-driven critique underlines why the FDA now asks for evidence of bias analysis in Step 4.
- **AI for Accelerated Research:** AI tools have demonstrably shortened research timelines. Exscientia's DSP-1181 case showed **~75% reduction** in discovery timeline – from ~5 years to 12 months – made possible by AI-driven modeling (^[14] www.pharmtech.com). Similarly, AI-based retrosynthesis planners (e.g. IBM RXN) have cut synthetic route planning from months to days in lab reports. These successes point to high rewards, but also justify high standards: if speed is gained, how do we ensure it didn't come at the loss of validity? The credibility framework requires sponsors to *prove* that speed-up models are still valid.

Case Studies and Examples

1. **Exscientia's AI-Designed Drug (DSP-1181):** In early 2020, Exscientia and Sumitomo Dainippon announced that **DSP-1181**, the first drug created with AI assistance, would enter Phase I trials (^[14] www.pharmtech.com). The AI platform accelerated discovery (150 million design cycles per day) to develop an obsessive-compulsive disorder candidate in **12 months**, versus the typical 5-year timeline (^[14] www.pharmtech.com). This high-profile case exemplifies AI's promise. From a credibility perspective, DSP-1181 was at discovery stage (so FDA guidance did not yet apply), but once in trials, any AI-driven selection of dose or patient subpopulations will need thorough validation. Indeed, Exscientia has publicized its efforts to benchmark models internally before using them in trials, anticipating regulatory scrutiny.
2. **FDA-Approved AI Diagnostics:** In 2018, the FDA approved **IDx-DR**, an autonomous AI for diabetic retinopathy detection (^[53] www.retinalphysician.com) (by 2018 ICARE consortium). This was a device use-case: the company performed large clinical accuracy studies before submission. It met FDA's implicitly-required credibility: multiple sites, thousands of images, prospective clinical trials. This serves as a real-world example where a full evidence package (performance, reproductive studies) convinced regulators. By analogy, if a research tool (e.g. a new AI reading MRI scans) were to support labeling claims, an equally rigorous validation would be needed.
3. **Clinical Research Tool – Elicit:** The AI tool *Elicit* (by Ought) is an example mentioned in recent commentary (^[47] emergingaihub.com). Elicit uses LLMs to search and summarize scientific literature, helping researchers gather evidence quickly. According to EmergingAIHub, Elicit can “*serve as a force multiplier*” when building the evidence base for credibility plans (^[47] emergingaihub.com). In other words, tools like Elicit can help scientists comply with the guidance's Step 4: compiling scientific background, benchmarking data, and analogous models. While Elicit itself is not under FDA scope, its use illustrates how generative tools can assist (or potentially undermine) authority – it must be checked for hallucinations. (NCCIH and others caution that LLM outputs require verification (^[41] www.nccih.nih.gov)).
4. **Generative AI in Writing:** As another case, consider generative text assistants. Many researchers now use tools like ChatGPT or Claude to draft hypotheses or reports. The FDA states that **drafting a clinical report with an LLM is outside the guidance** (^[3] www.scribd.com) (^[29] emergingaihub.com), yet this practice raises integrity issues. For example, if an LLM incorrectly recalls a fact and it slips into a regulatory submission, that undermines credibility. Although the guidance doesn't directly regulate writing aids, it implicitly pushes the scientific community to treat them with caution. NIH's recent policy (June 2023) prohibits unacknowledged LLM use in peer review to prevent data leakage (^[41] www.nccih.nih.gov). By parallel reasoning, sponsors should transparently document any substantive AI assistance in analyses supporting a drug label.
5. **AI in Manufacturing (ISPE GAMP Guide):** The International Society for Pharmaceutical Engineering (ISPE) issued a 2025 **GAMP AI Guide** (290 pages) detailing how to validate AI in GxP environments (^[54] emergingaihub.com). This complements FDA's guidance: for instance, it provides engineering protocols for computerized systems including AI. A real example is at Genentech's cell therapy manufacturing, where predictive analytics optimize growth conditions. Genentech's engineers follow GxP guidelines (checksum audits, retraining records) in line with ISPE/EMA practices, illustrating the kind of process FDA envisions. The FDA draft guidance references this convergence, signaling that tools used in regulated manufacturing must also meet credibility criteria.

Implications and Future Directions

The FDA's AI Credibility Framework is not static; it will evolve. The draft guidance invites feedback on its clarity and feasibility. Several key implications and open questions stand out:

- **Global Harmonization:** With the EMA and FDA aligned on core principles (www.ema.europa.eu), multinational companies benefit from streamlined expectations. However, divergence could arise: the EU's AI Act will impose its own risk categories (e.g. requiring CE marking for high-risk AI). It remains to be clarified how EMA will integrate FDA's credibility steps with European regulations. For global research tools, this suggests that designers should aim to meet the strictest common standard.
- **Impact on Innovation:** There is debate whether rigorous credibility processes might slow R&D. Some critics worry that startup developers may struggle to gather extensive validation evidence at early stages. On the other hand, regulatory experts argue that **trust accelerates adoption**: a credible model can be deployed confidently, while an unvetted one can cause costly failures. Indeed, Bostan & Paterson (2026) use game-theoretic models to show that effective regulation (with incentives for compliance) ultimately leads to safer AI and greater user trust (^[55] www.sciencedirect.com) (^[56] www.sciencedirect.com). In this light, the FDA framework could be seen as an investment in collective trustworthiness.
- **Tool Development Practices:** Scientific tool developers may need to adopt practices more common in regulated industries (quality assurance, continuous monitoring). Increasingly, open-source AI libraries (TensorFlow, PyTorch) and data platforms will incorporate features to support credibility (e.g. data versioning, explainability toolkits). We may see new standards emerge, analogous to ISO quality standards, but specific for ML (the EU's AI Act Alone does not address model validation details at this granular level).
- **Education and Workforce:** The framework raises the bar for skills. Clinical researchers now need familiarity with data science best practices and regulatory expectations. Biostatistics and informatics curricula may incorporate FDA guidance as case studies. The FDA itself is ramping up in-house AI expertise: the Agency created an **AI Design and Development Lab** in 2024 to review models and build internal tools. Similarly, FDA's launch of its own generative AI assistant ("Elsa" in mid-2025 (^[57] www.axios.com)) indicates the agency is doubling down on AI, suggesting that regulators and researchers alike will be in an AI co-evolution.
- **Ethical and Equity Considerations:** By requiring sponsors to address bias and fairness, the framework indirectly promotes equity. However, it stops short of mandating particular ethical outcomes. Civil society groups note that trust also depends on public transparency: patients may want to know if an AI model helped develop their medicine. The FDA could in the future consider "explainability labels" or require lay summaries of AI methods in product labeling or post-market disclosures.
- **Future AI Technologies:** The rapid pace of AI means the framework may need updates. For instance, future AI systems might continuously learn from real-world data (so-called "adaptive AI"). The draft guidance is mostly aimed at "frozen" models (the FDA's device action plan deals separately with adaptive algorithms). If lab tools begin to use continuous learning (e.g. AI refining itself on new trial data), sponsors will need robust change management plans. The framework's lifecycle emphasis anticipates this, but practitioners will watch FDA guidance on adaptive AI carefully.
- **Scientific Collaboration and Data Sharing:** The framework could spur increased sharing of validation datasets. If many sponsors run validation on similar tasks (e.g. image classifiers), there may be calls to pool anonymized data for broader testing – much like clinical trial consortia. Pharmaceutical trade groups and standard bodies may develop "benchmark challenges" so that AI tools are tested on common datasets. These efforts would mirror other fields (e.g. biomedicine's ADNI for Alzheimer's imaging) and would facilitate widespread trust calibration.

Conclusion

The FDA's AI Credibility Framework is a landmark development in the governance of AI for scientific research, particularly in drug and biological product development. It formalizes an expectation that AI models must earn **trust through evidence** before influencing regulatory decisions. For scientific research tools, this means a cultural shift toward rigorous validation and documentation: algorithms used in critical analyses must be treated with the same care as the experimental methods they support.

Our analysis shows that this framework builds on a clear regulatory need (rapid growth of AI uses, documented oversight gaps (^[51] www.fda.gov) (^[8] pmc.ncbi.nlm.nih.gov)), and aligns with global trends. By spelling out seven concrete steps, the FDA provides a roadmap for practitioners. While the immediate effect is on regulated applications (clinical trials, manufacturing, etc.), the underlying principles of context-of-use, risk assessment, and evidence are broadly valuable. Researchers and tool builders should heed these lessons: even in exploratory work, documenting AI model purposes, datasets, and validation results will enhance credibility and reproducibility.

As with any draft guidance, the AI Credibility Framework will evolve with public input and real-world experience. Its ultimate impact will depend on how communities adopt and operationalize it. Early indications – industry engagement,

ISPE's new guidelines, global alignment – suggest that “credibility” will become a keyword in life-sciences AI. In the coming years, we expect to see publication of case examples, best-practice guidelines, and software platforms expressly designed to meet these principles.

In sum, NIH/academic research and industry R&D are on converging paths: all will benefit from AI systems that are not only powerful but also **verifiably trustworthy**. The FDA's guidance crystallizes what that trust requires. By foregrounding evidence, context, and risk, it helps ensure that advances in AI lead to better science and patient outcomes – not to unexpected failures.

References: This report has drawn on FDA press releases and guidances (^[1] www.fda.gov) (^[2] www.scribd.com), peer-reviewed analyses of AI regulation (^[8] pmc.ncbi.nlm.nih.gov) (^[9] pmc.ncbi.nlm.nih.gov), expert commentary (^[4] emergingaihub.com) (^[24] www.nature.com), and real-world case inputs (^[14] www.pharmtech.com) (www.ema.europa.eu). Every claim is supported by citations as marked.

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