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# FDA AI Credibility Framework: Impact on Research Tools

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# 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. Issued as draft guidance in January 2025, the framework proposes a **risk-based, 7-step process** for assessing the credibility of AI model outputs used to support regulatory decisions about drug safety, effectiveness, or quality (FDA guidance; FDA draft, section IV.A). **Credibility** means trust in model performance for a particular **context of use (COU)**, established through credibility evidence (FDA draft, section I). The draft excludes drug-discovery uses and operational-efficiency uses that do not impact patient safety, drug quality, or study-result reliability (FDA draft, section II).

For scientific research tools, the framework offers proposed, risk-based recommendations for assessing AI credibility. FDA labels the January 2025 guidance as draft, not for implementation, and nonbinding (FDA guidance status). Sponsors may use alternative approaches that satisfy applicable statutes and regulations (FDA draft, p. 1). Existing legal requirements apply independently of this proposed assessment approach. 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 (pmc.ncbi.nlm.nih.gov), (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" (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 (pmc.ncbi.nlm.nih.gov) (FDA draft, section III). 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** (pmc.ncbi.nlm.nih.gov), dramatically accelerating biomedical discovery. Pharmaceutical companies increasingly rely on AI for target identification, in silico trials, and optimization of manufacturing. In GlobalData's 2020 industry outlook survey, **65% of the pharma managers and executives surveyed** selected big data (32%) or AI (33%) as the technology expected to have the greatest industry impact in 2020 (GlobalData, February 5, 2020). 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 (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 (pmc.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** (pmc.ncbi.nlm.nih.gov) (FDA draft, section III). 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 (pmc.ncbi.nlm.nih.gov). These gaps fuel a "false sense of security" when AI outputs are integrated into critical decisions (pmc.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) (pmc.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"** (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"* (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 (www.fda.gov) (FDA draft, section I). It was informed by broad stakeholder input (over 800 public comments and expert workshops) (www.fda.gov) and reflects FDA's experience evaluating **500+ AI-containing submissions since 2016** (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 (www.fda.gov) (FDA draft, section II). 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). Under Article 6(1) of Europe's AI Act, high-risk classification applies when an AI system is a product or safety component covered by Annex I legislation and the relevant product requires third-party conformity assessment. Annex III identifies additional high-risk use cases, subject to Article 6's exceptions (EU AI Act, Article 6). 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 (pmc.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** | AI producing information or data to support regulatory decisions about drug safety, effectiveness, or quality (FDA draft, section II) | Risk-based credibility assessment of AI model outputs for a particular COU (FDA draft, section I) | Draft Level 1 Guidance (January 2025); not for implementation; nonbinding recommendations (FDA guidance status). |
| FDA AI/ML Action Plan (2021) | Medical devices and software (SaMD) | Total product lifecycle oversight; Good ML Practices; adaptive algorithms (pmc.ncbi.nlm.nih.gov) | Finalized action plan. (Platform for device AI regulation) |
| **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) | Cross-sector AI regulation, including relevant healthcare uses | Prohibited practices are distinct from high-risk systems, which face risk assessment, documentation, and human-oversight obligations | Phased application: the original prohibitions took effect in February 2025; the Commission's current timetable places Annex III high-risk rules on 2 December 2027 and Annex I product-system rules on 2 August 2028 (European Commission). |
| **NIST AI RMF 1.0** (Jan 2023) | All domains (voluntary, US) | Framework for trustworthy AI (risk management steps) | Published by NIST (Jan 2023) (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 AI used to produce information or data supporting regulatory decisions about drug safety, effectiveness, or quality (FDA draft, section II). Its use of "drug product life cycle" includes nonclinical, clinical, postmarketing and manufacturing phases; drug discovery is excluded (FDA draft, footnote 10).

By contrast, the draft does not address AI used in **drug discovery**, or AI used for operational efficiencies—including drafting a regulatory submission—that do not impact patient safety, drug quality, or the reliability of nonclinical or clinical study results. These are exclusions from this draft's scope, not assurances that an activity is outside all FDA oversight (FDA draft, section II).

The FDA lists the document as **Draft Level 1 Guidance**, not for implementation, with nonbinding recommendations (FDA guidance status). The draft says it will represent FDA's current thinking when finalized, does not establish rights, and is not binding on FDA or the public. Sponsors may use an alternative approach if it satisfies applicable statutes and regulations (FDA draft, p. 1). The framework's high-level concepts were informed by ASME V&V40, a standard developed for physics-based models in medical-device applications (FDA draft, footnote 13). FDA also applies benefit-risk principles when assessing drug safety, effectiveness, and quality (FDA draft, footnote 12).

## 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 (FDA draft, sections I and IV.A.1–2). For sponsors choosing this draft approach, Steps 1 and 2 recommend stating the *question of interest* the model addresses and defining its COU. The COU defines the model's specific role and scope in addressing that question (FDA draft, section I). 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.

Once COU is defined, the draft proposes **assessing AI model risk (Step 3)** using model influence and decision consequence (FDA draft, section IV.A.3). Credibility assessment activities and documentation should be commensurate with model risk and tailored to the specific COU (FDA draft, section II).

Crucially, the framework defines **credibility** as trust in an AI model's performance for a particular COU, established through credibility evidence. Such evidence is any evidence that could support the credibility of the model's output for that COU (FDA draft, section I). For sponsors choosing this approach, Steps 4–7 recommend planning, executing and documenting a credibility assessment, then determining adequacy for the COU. Lifecycle maintenance is discussed separately for relevant uses in section IV.B (FDA draft, sections IV.A–B).

## The 7-Step Credibility Assessment Framework

The draft describes **seven steps** for sponsors choosing its risk-based credibility assessment approach. The following roadmap summarizes section IV.A of the official draft (FDA draft, section IV.A):

| Step | Focus / Objective | Description / Activities |
|---|---|---|
| 1. **Define Question of Interest** | Precisely articulate the question the AI model will answer. | The draft recommends defining the specific question, decision, or concern addressed by the model (FDA draft, section IV.A.1). |
| 2. **Define Context of Use (COU)** | Specify how the model will be used in decision-making. | Define the model's specific role and scope in addressing the question of interest (FDA draft, section IV.A.2). |
| 3. **Assess Model Risk** | Evaluate model *influence* vs *consequence* to determine risk level. | Assess model influence and the consequences of an incorrect decision (FDA draft, section IV.A.3). |
| 4. **Develop Credibility Plan** | Plan validation activities to demonstrate model reliability. | Select assessment activities proportionate to model risk and COU; describe model development and evaluation as applicable (FDA draft, section IV.A.4). |
| 5. **Execute the Plan** | Run the planned credibility assessment activities and gather evidence. | FDA describes executing the assessment plan; prior discussion with FDA may help set expectations and identify challenges (FDA draft, section IV.A.5). Determine Part 11 applicability for specific records under the relevant predicate rules; this step does not create a universal real-time audit requirement for every decision (FDA Part 11 scope guidance, section III.B.2). |
| 6. **Document Results** | Report findings, analyses, and any deviations from plan. | Document results and deviations. Discuss with FDA whether, when, and where to submit the report (FDA draft, section IV.A.6). |
| 7. **Determine Adequacy** | Make a final judgment on model fitness for the COU. | Assess whether the model's credibility is sufficient for its risk and COU. Consider lifecycle maintenance where relevant (FDA draft, sections IV.A.7 and IV.B). |

The seven steps are set out in section IV.A.1–7 of the FDA draft. Sponsors should consult those sections for the detailed recommendations (FDA draft, section IV.A).

Several points merit emphasis:

- **Document Everything:** Preserve relevant datasets, code, parameter choices, model versions, and results to support reproducibility. Determine legal retention and electronic-record controls record by record under applicable predicate rules and electronic-submission requirements. A record used to generate a submission is not automatically a Part 11 record: it must itself be submitted electronically

within Part 11's scope, or otherwise be required under a predicate rule and maintained electronically. Apply validation, audit-trail, and retention requirements according to that assessment and FDA's stated enforcement policy (FDA Part 11 scope guidance, sections III.B.2–3).

- **Transparency on Deviations:** For sponsors choosing the draft approach, Step 6 recommends documenting assessment results and deviations from the plan (FDA draft, section IV.A.6). 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 (pmc.ncbi.nlm.nih.gov).
- **Lifecycle Accountability:** Section IV.B discusses lifecycle maintenance for relevant uses, including manufacturing models. It recommends ongoing performance monitoring and oversight proportionate to model risk and COU (FDA draft, section IV.B).

### 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 (FDA draft, footnote 13). 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) (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 (pmc.ncbi.nlm.nih.gov) (www.nccih.nih.gov).

## In-Scope Uses and Compliance Needs

For AI used to support regulatory decisions about a drug’s safety, effectiveness, or quality, FDA proposes a risk-based credibility assessment. This draft is nonbinding and not for implementation; alternative approaches may satisfy applicable law (FDA guidance status; FDA draft, p. 1). Consider these examples as illustrations of the proposed recommendations:

- **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. For sponsors choosing the draft approach, credibility assessment activities should be proportionate to AI model risk and tailored to the specific COU (FDA draft, section IV.A.3–4). In practice, trial sponsors using such tools should 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 (FDA draft, section IV.A.4) (pmc.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 draft recommends tailoring credibility assessment activities to model risk and COU (FDA draft, section IV.A). In such cases, the tool should have a 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 (FDA draft, section II). A high-risk scenario would be an AI model that autonomously controls a sterile manufacturing line; here, a risk-proportionate credibility assessment could include 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 warrant evidence of performance (false positive/negative rates) but fall under a lighter validation regime.

For sponsors and tool vendors, these proposed recommendations favor **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 should document its development and performance: changes or updates may warrant 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 (www.fda.gov), much as companies do now for complex trial designs.

## Out-of-Scope but Best Practice

The FDA draft excludes AI used in drug discovery and AI used for operational efficiencies—such as internal workflows, resource allocation, or drafting a regulatory submission—when those operational uses do not impact patient safety, drug quality, or the reliability of nonclinical or clinical study results. It encourages early FDA engagement when sponsors are uncertain whether a use falls within its scope (FDA draft, section II). These uses, however, still raise important issues like confidentiality, data provenance, and plagiarism that NIH and other institutions are grappling with (www.nccih.nih.gov) (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 (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 (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 (pmc.ncbi.nlm.nih.gov) (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 | Depends on the use | Assess whether the AI produces information or data to support regulatory decisions about drug safety, effectiveness, or quality (FDA draft, section II). |
| **AI Patient Matching** (EHR analysis) | Clinical trial enrollment | In scope (clinical) | For sponsors choosing the draft approach, define the COU and tailor credibility assessment to model risk (FDA draft, section II). |
| **Machine Vision Tumor Sizing** (imaging AI) | Endpoint measurement | In scope (clinical) | For sponsors choosing the draft approach, tailor credibility assessment to model risk and COU (FDA draft, section II). |
| **Predictive PK/PD Modeling** (equation learning) | Preclinical modeling | In scope (nonclinical to clinical) | For sponsors choosing the draft approach, tailor credibility assessment to model risk and COU (FDA draft, section II). |
| **Postmarket Adverse Event NLP** (AE mining) | Pharmacovigilance | In scope (postmarket) | For sponsors choosing the draft approach, tailor credibility assessment to model risk and COU (FDA draft, section II). |
| **Manufacturing AI** (process optimization) | Drug manufacturing | In scope (manufacturing controls) | For sponsors choosing the draft approach, tailor credibility assessment to model risk and COU (FDA draft, section II). |
| **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) (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), sponsors can consider the draft framework's recommendations. The draft does not create a mandatory retrospective assessment procedure; alternative approaches may satisfy

applicable statutes and regulations (FDA draft, p. 1). 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 draft recommends documentation proportionate to model risk and tailored to the COU (FDA draft, section II). Researchers can also apply transparency and reproducibility practices in exploratory work (pmc.ncbi.nlm.nih.gov) (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

In its January 6, 2025 announcement, FDA reported experience with **more than 500 drug and biological product submissions with AI components since 2016** (FDA). This is a count of submissions involving drugs and biological products, not a count of authorized AI medical devices.

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

These analyses support careful evaluation of AI models. For sponsors choosing the FDA draft's approach, credibility assessment activities and documentation should be proportionate to model risk and tailored to the context of use. These are proposed, nonbinding recommendations, not universal submission, bias-audit, or demographic subgroup-reporting mandates. Section IV.A.6 recommends discussing with FDA whether, when, and where to submit the credibility assessment report (FDA draft, sections I, II and IV.A.6).

## 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" (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).

FDA encourages sponsors to engage early with the agency about AI credibility assessment and AI use in drug development (FDA). 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 EMA–FDA principles support international convergence through broad guidance on AI use across the medicines lifecycle. They will inform future guidance in the respective jurisdictions; they do not establish automatic cross-acceptance of credibility plans. EMA states that additional EU guidance will take account of applicable legal requirements and new EU medicines legislation (EMA).

## Data and Statistics: AI in Life Sciences

To quantify the setting, consider these figures and trends:

- **Regulatory Filings:** FDA's January 6, 2025 announcement described experience with **more than 500 drug and biological product submissions with AI components since 2016** (FDA).
- **Technological Expectations:** GlobalData reported that 33% of the pharma managers and executives surveyed for its 2020 industry outlook selected AI as the technology expected to have the greatest industry impact in 2020 (GlobalData, February 5, 2020).
- **Validation Gap:** Abulibdeh et al. reported that many AI healthcare tools lacked clear evidence of clinical benefit or generalizability, and that testing procedures, validation cohorts, and bias-mitigation details were often missing (Abulibdeh et al., 2025).
- **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 (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? For AI outputs supporting regulatory decisions about drugs, FDA proposes a risk-based credibility assessment framework (FDA guidance).

### Case Studies and Examples

1. **Exscientia's AI-Designed Drug (DSP-1181):** In their January 30, 2020 announcement, Sumitomo Dainippon Pharma and Exscientia reported that a Phase I study of DSP-1181 had begun in Japan for obsessive-compulsive disorder. The sponsors reported **less than 12 months for the exploratory research phase**, compared with a conventional average of **4.5 years**; this comparison concerns exploratory research, not the full clinical-development timeline (sponsor announcement).
2. **FDA De Novo Authorization — IDx-DR:** FDA granted the De Novo request for **IDx-DR**, submitted by **IDx, LLC**, on April 11, 2018, establishing Class II classification (FDA record; classification order). The authorized indication is automatic detection of more-than-mild diabetic retinopathy in adults diagnosed with diabetes who have not previously been diagnosed with diabetic retinopathy, using the Topcon NW400 (FDA decision summary, p. 1).
3. **Clinical Research Tool – Elicit:** Elicit's official site describes research briefs based on a process inspired by systematic reviews (Elicit). Researchers should check the underlying papers before relying on such summaries in a credibility assessment.
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 draft excludes operational-efficiency uses, such as drafting a regulatory submission, when they do not impact patient safety, drug quality, or the reliability of nonclinical or clinical study results (FDA draft, section II), 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 June 23, 2023 notice prohibits scientific peer reviewers from using generative AI to analyze applications or formulate peer-review critiques. Uploading or sharing confidential application content or original concepts with online generative AI tools violates NIH confidentiality requirements. Accessibility technologies may receive an exception, but reviewers must communicate with their designated NIH official before use (NIH notice NOT-OD-23-149). By parallel reasoning, sponsors should transparently document any substantive AI assistance in analyses supporting a drug label.
5. **AI in Manufacturing (ISPE GAMP Guide):** ISPE's **GAMP® Guide: Artificial Intelligence** discusses principles and practices relevant to the design, development, operation, and use of AI (ISPE guide).

## 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. Alalawi et al. (2026) use evolutionary game theory to model AI regulation. Their results make incentives for effective regulation necessary for trustworthy AI and user trust. They also find that conditioning user trust on regulator effectiveness is insufficient to support safe development and AI adoption when implementation costs are high (published paper, Fig. 7; authors' preprint, abstract). 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. FDA also uses AI internally: on June 2, 2025, it launched Elsa, a generative AI tool intended to help employees, including scientific reviewers and investigators, work more efficiently (FDA launch announcement).
- **Ethical and Equity Considerations:** The draft recommends describing potential biases among the limitations of the modeling approach (FDA draft, section IV.A.4.b). 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 (www.fda.gov) (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 (www.fda.gov) (FDA draft guidance), peer-reviewed analyses of AI regulation (pmc.ncbi.nlm.nih.gov), expert commentary (www.nature.com), and real-world case inputs (www.pharmtech.com) (www.ema.europa.eu). Every claim is supported by citations as marked.

## Source links

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

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