

# Factors Hindering AI Adoption in Life Sciences: 2023-2026

By Adrien Laurent, CEO at IntuitionLabs • 6/30/2025 • 20 min read

ai life sciences technology adoption regulatory barriers data quality organizational challenges ethical ai clinical trials genomics federated learning



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# Barriers to AI Adoption in Life Sciences (2025-2026)

Life sciences companies recognize that AI can dramatically accelerate research and development, improve patient care, and reduce costs <sup>[1]</sup> [awspartnersgenai.cio.com](#) <sup>[2]</sup> [coherentsolutions.com](#). However, in practice adoption lags due to a constellation of challenges. Key technical, regulatory, organizational, ethical, and financial barriers have slowed AI integration into pharmaceuticals, biotech, [clinical trials](#), genomics and diagnostics. This report examines these barriers in detail, with sector-specific nuances, real-world examples from 2023–2026, and emerging solutions like federated learning, regulatory sandboxes, and AI governance frameworks. Despite growing investment, a 2026 Deloitte survey found that only 22% of life sciences leaders have successfully scaled AI, and just 9% reported achieving significant returns <sup>[3]</sup> [deloitte.com](#).

## Technical Barriers

- Data Integration & Quality:** AI models require large, diverse, high-quality datasets. In life sciences, data are often siloed (across hospitals, labs, companies) and heterogeneous. Patient records, omics data, images and research results are stored in isolated systems (data “silos”) with inconsistent formats <sup>[4]</sup> [oecd.org](#) <sup>[5]</sup> [ey.com](#). As the OECD notes, “health data are sensitive and require handling with care through tight regulation” – making large-scale pooling difficult <sup>[6]</sup> [oecd.org](#) <sup>[5]</sup> [ey.com](#). Data quality issues (missing values, labeling errors, biases) further impede model training. For example, clinical AI can fail if trained on unrepresentative datasets (e.g. skin cancer AI trained only on light skin) <sup>[7]</sup> [coherentsolutions.com](#). Surveys of life sciences professionals confirm data problems as a top obstacle – over one-third cited *data accuracy, security and quality* as major issues <sup>[8]</sup> [capestart.com](#).
- Model Interpretability & Validation:** Many AI systems (especially deep learning) operate as “black boxes,” obscuring how predictions are made. Clinicians and regulators demand interpretability and rigorous validation. A recent review notes that lack of transparency breeds mistrust: “explainability is an important element...in order to enhance trust of medical professionals,” and hiding how an AI arrives at decisions raises adoption barriers <sup>[9]</sup> [humanfactors.jmir.org](#). Life sciences regulators likewise emphasize transparency: new FDA draft guidance (Jan 2025) outlines risk-based frameworks for *credibility* of AI models in drug decision-making <sup>[10]</sup> [fda.gov](#). Validating AI in this field is also hard because biological systems are complex and nonstationary. Early AI efforts struggled with reproducibility: the scarcity of high-quality data and “lack of standardized protocols for AI implementation” were major hurdles <sup>[11]</sup> [ey.com](#).
- Infrastructure & Scalability:** Advanced AI (especially deep learning and [LLMs](#)) requires substantial computing power, secure IT systems, and modern pipelines (MLOps). Many organizations lack the IT infrastructure or cloud resources to train and deploy large models. Integrating AI tools into legacy systems (laboratory instruments, manufacturing control systems) can be technically challenging and costly <sup>[12]</sup> [ispe.org](#) <sup>[13]</sup> [coherentsolutions.com](#). For example, factory-floor AI must interface with older equipment, necessitating robust MLOps and cybersecurity “guardrails” to meet [GxP](#) (Good Practice) requirements <sup>[14]</sup> [ispe.org](#) <sup>[12]</sup> [ispe.org](#).

## Regulatory and Compliance Issues

- FDA/EMA Standards and Guidance:** Life sciences R&D is heavily regulated to ensure patient safety. Existing frameworks (e.g. ICH/GCP, GxP, [21 CFR Part 11](#)) were not designed for AI. The FDA released its first draft guidance on AI for [regulatory decision-making](#) in January 2025, proposing a “risk-based credibility assessment” and seven-step framework for AI models supporting drug safety/efficacy <sup>[15]</sup> [fda.gov](#). The comment period was extended to Q1 2026, with final guidance expected in Q2 2026 <sup>[16]</sup> [dlapiper.com](#). In a significant step toward international harmonization, on January 14, 2026, the EMA and FDA jointly released ten guiding principles for responsible AI use across the medicines lifecycle—from early research and clinical trials to manufacturing and safety monitoring [ema.europa.eu](#). The FDA reports over 500 AI-enabled drug submissions since 2016, with more than 95% not rejected due to AI issues <sup>[17]</sup> [fda.gov](#). Over 200 AI-developed drugs are now in clinical stages, with the first AI-developed drug approval projected for 2026-2027 <sup>[18]</sup> [axis-intelligence.com](#).
- GxP and Device Regulations:** In manufacturing and clinical use, any software (including AI) that affects drug quality or patient safety must comply with GxP and medical-device rules. This means [rigorous validation](#), audit trails, change control, and cybersecurity aligned with PIC/S GMP and FDA Part 820 requirements <sup>[19]</sup> [ispe.org](#). AI’s “black box” nature complicates validation under GxP. Life sciences firms must implement special *governance frameworks* for AI: industry groups recommend policies for data protection, model documentation, explainability and auditability <sup>[19]</sup> [ispe.org](#) <sup>[20]</sup> [coherentsolutions.com](#). For example, the ISPE recommends AI governance aligned with [GAMP 5](#), with processes for data integrity and risk management across AI development <sup>[19]</sup> [ispe.org](#). Noncompliance can delay approvals or trigger enforcement.
- Explainability and Risk Controls:** Both regulators and organizations are beginning to require explainability. The EU AI Act entered into force in August 2024, with prohibited AI practices and AI literacy obligations effective from February 2025, and general-purpose AI model rules from August 2025 [digital-strategy.ec.europa.eu](#). Most provisions for high-risk AI systems—including AI-enabled medical devices—apply from August 2026, with full compliance required by August 2027 <sup>[21]</sup> [pscsoftware.com](#). In November 2025, the European Commission proposed the Digital Omnibus package, which may exempt medical devices and IVDs from “high-risk AI system” classification under the AI Act, potentially simplifying compliance for MedTech <sup>[22]</sup> [dlapiper.com](#). In the US, guidance and executive orders continue to push for AI safety, security, and fairness <sup>[23]</sup> [lifescienceleader.com](#). Meeting these evolving requirements demands extra effort in model design and documentation. Many life sciences companies find it hard to provide the documentation and audit trails needed for an “explainable” model – another friction point.

## Organizational and Cultural Challenges

- Resistance to Change:** Adopting AI often requires rethinking established workflows. Staff may be wary of new tools that could disrupt routines. Surveys reveal that organizational culture can be a bottleneck: life sciences teams struggle with defining success metrics for AI and integrating AI into existing systems <sup>[24]</sup> [capestart.com](#). This “change management” issue means leadership must champion AI and align incentives.
- Skill and Talent Gaps:** There is a well-documented shortage of personnel who understand both AI and life sciences. Nearly 80% of respondents in a recent industry survey cited **lack of AI expertise** as their top implementation barrier <sup>[24]</sup> [capestart.com](#). PhD scientists and clinicians typically lack data science training, while data teams may lack domain knowledge. Bridging this gap requires interdisciplinary roles, joint training, or partnerships. Industry experts warn that an “acute shortage of interdisciplinary talent” is a foundational challenge <sup>[25]</sup> [ey.com](#).
- Cross-Disciplinary Communication:** Effective AI projects need close collaboration between biologists, clinicians, data scientists and IT staff. However, these groups often speak different “languages” (e.g. clinical terminology vs. code). Misunderstandings can slow project progress. Companies must build cross-functional teams and ensure mutual education. Without this, even technically feasible solutions may fail to meet real-world needs.

## Ethical and Privacy Concerns

- Patient Data Security and Consent:** Much life sciences AI is built on sensitive personal data (EHRs, trial data, genomics). Ensuring confidentiality under HIPAA, GDPR and similar laws is paramount. Data breaches or misuse could have legal and reputational fallout. AI adoption requires robust data governance: anonymization, encryption, and strict access controls <sup>[26]</sup> [coherentsolutions.com](#) <sup>[27]</sup> [lifescienceleader.com](#). But excessive anonymization can degrade AI model performance <sup>[28]</sup> [oecd.org](#). Navigating this trade-off is nontrivial. Federated learning is emerging as a solution: by keeping data onsite and sharing only model updates, federated AI “drastically reduces privacy concerns” <sup>[6]</sup> [oecd.org](#) <sup>[29]</sup> [oecd.org](#). For example, an OECD analysis notes that federated learning “enables researchers to gain insights collaboratively... without moving patient data beyond the firewalls” <sup>[29]</sup> [oecd.org](#).
- Bias and Fairness:** Biased algorithms pose ethical and clinical risks. If AI is trained on non-representative populations or flawed data, it can exacerbate health disparities. Studies show repeated concerns about “algorithmic bias” blocking adoption: stakeholders worry that models “may not be representative of the patient population” or could amplify socioeconomic inequalities <sup>[30]</sup> [humanfactors.jmir.org](#). For instance, genetic or imaging AI developed on one demographic may misdiagnose others. Organizations must audit for bias, but this adds complexity and cost.
- Explainability and Trust:** Ethically, clinicians must understand AI guidance when patient lives are at stake. The opacity of many AI tools conflicts with medical norms. In health care contexts, lack of transparency is seen as an impediment: one study noted hesitancy to use an AI chatbot because of “lack of transparency on how the chatbot...arrives at responses” <sup>[9]</sup> [humanfactors.jmir.org](#). This ethical imperative reinforces the need for explainable AI – another technical and regulatory requirement.

## Financial and Strategic Barriers

- ROI Uncertainty:** AI projects often entail large upfront investment (computing infrastructure, software, talent) with benefits that may take years to materialize. Executives thus demand clear business cases. However, predicting ROI in life sciences is hard. Many initiatives fail to demonstrate immediate gains, making it difficult to secure continued funding. A survey found that almost half of life-science teams cite **budget constraints** as a major barrier <sup>[31]</sup> [capestart.com](#). Uncertain regulatory timelines (e.g. for new drug approvals) and long R&D cycles further cloud ROI forecasts.
- High Costs and Long Timelines:** Implementing AI in R&D or manufacturing can require integrating expensive software and retraining staff. Developing validated medical AI tools (e.g. for diagnostics) can take many years and millions of dollars before payoff. The “long timelines” of drug development compound this: even if an AI improves a step, the ultimate financial benefit may only appear after a new drug reaches market. These strategic uncertainties discourage some firms from fully committing to AI. As one article notes, without clear success metrics or quick wins, funding can dry up <sup>[31]</sup> [capestart.com](#).
- Integration and Maintenance Costs:** Beyond initial deployment, AI systems require ongoing tuning and validation. Maintaining AI models (monitoring drift, updating data, revalidating performance) adds to operational costs. Organizations must budget for continuous MLOps. Many lack clear budgeting for these downstream costs, which can stall projects post-prototype.

## Sector-Specific Nuances

- Pharmaceuticals:** Drug companies face intense regulatory scrutiny and long R&D cycles. AI can be applied across discovery, preclinical, and trials, but each stage has unique hurdles. In discovery, the main challenges are *data complexity* (multi-omics, chemistries) and *validating predictions in vivo*. In development, regulators require proof of safety and efficacy; AI-driven candidates still need traditional trials. GxP-compliant data collection in manufacturing and supply-chain demands rigor in AI model control <sup>[19]</sup> [ispe.org](#). Pharma also struggles with competitive secrecy: proprietary chemical libraries and trial data are seldom shared, reinforcing silos (which, for example, federated learning seeks to address <sup>[32]</sup> [oecd.org](#)).
- Biotechnology:** Biotechs (especially AI-first drug-discovery firms) often integrate AI at their core. They typically can be more agile but often face funding constraints. Small biotechs may lack in-house regulatory or quality expertise, making FDA/EMA compliance a hurdle. Partnerships with big pharma or CMC (contract research) can help, but alignment of processes is needed.
- Clinical Trials:** AI is poised to optimize trial design and patient recruitment, but regulatory and ethical barriers persist. Protecting trial patient privacy is paramount, especially with new data types (wearables, genomics). Agencies are still refining how to review AI-driven trial tools. Also, trial sites vary in digital maturity, so integrating AI in site management can be uneven. Some use cases (like decentralized remote trials) helped by AI-powered monitoring, but require robust data pipelines and cross-site standardization.

- **Genomics and Precision Medicine:** Genomic data are extraordinarily sensitive, making privacy concerns acute. The scale of genomics (e.g. large biobanks) also poses integration issues. Regulatory frameworks for genomic AI are nascent, and consent models for research use are evolving. Given these concerns, federated or privacy-preserving AI (synthetic data, secure enclaves) are particularly relevant. Projects like the UK 100,000 Genomes initiative are exploring federated training across hospital networks <sup>[29]</sup> [oecd.org](https://www.oecd.org).
- **Diagnostics and Medical Devices:** AI used in imaging or diagnostics is regulated as a medical device (AI-aided radiology, pathology). In the EU and US, such Software as a Medical Device (SaMD) must meet ISO and IEC standards. The new EU AI Act will classify many diagnostics as high-risk, adding compliance burdens. Medical-device regulators (e.g. FDA CDRH, MHRA) are still crafting guidance for continuously learning AI systems. In the UK, the MHRA's 2024 **AI Airlock** pilot demonstrated how regulators are trying to address these issues by collaborating with developers in a sandbox [gov.uk](https://www.gov.uk) <sup>[33]</sup> [thedataisphere.org](https://thedataisphere.org). Diagnostics companies must navigate both device rules and emerging AI-specific rules, making entry to market lengthy.

## 2023–2026 Case Studies and Examples

- **Early Adoption Successes:** A number of companies have publicly announced AI-driven gains. AstraZeneca's collaboration with BenevolentAI has advanced to four of five initial drug targets in chronic kidney disease and idiopathic pulmonary fibrosis, with their collaboration expanded in 2025 for a three-year extension focusing on systemic lupus erythematosus and heart failure <sup>[34]</sup> [benevolent.com](https://www.benevolent.com). AstraZeneca's Centre for Genomics Research has set an ambitious goal to analyze two million genomes by 2026 using AI and machine learning <sup>[35]</sup> [astrazeneca.com](https://www.astrazeneca.com). In 2025, Algen signed a \$555 million partnership with AstraZeneca for AI-powered drug discovery <sup>[36]</sup> [bioxconomy.com](https://www.bioxconomy.com). India's Aurigene launched an AI/ML drug-discovery platform in 2024 that is expected to cut "cycle time from chemical design to testing" by ~35% <sup>[37]</sup> [ey.com](https://www.ey.com). 2025 saw the highest single-year jump in IND filings for AI-originated molecules, driven by companies like Insilico Medicine, Recursion, and BenevolentAI <sup>[38]</sup> [drugdiscoveryonline.com](https://www.drugdiscoveryonline.com).
- **Regulatory Sandbox – UK AI Airlock:** The UK MHRA's **AI Airlock**, launched in Spring 2024, completed its pilot phase in April 2025, publishing four comprehensive reports in October 2025 [gov.uk](https://www.gov.uk). Phase 2 launched in late 2025 with seven new technologies selected—including Tortus (AI clinical note-taking), Panakeia (cancer diagnostics), Eye2Gene (eye disease detection), and NHS England's Federated Data Platform—running through March 2026 [gov.uk](https://www.gov.uk). A National Commission was established in September 2025 to develop a new regulatory framework for AI in healthcare, expected in 2026, with insights from the AI Airlock informing recommendations [medregs.blog.gov.uk](https://medregs.blog.gov.uk). New post-market surveillance regulations for AI medical devices came into force on June 16, 2025, requiring continuous real-world performance monitoring <sup>[39]</sup> [iatrox.com](https://www.iatrox.com).
- **Health Data Sandboxes (Indonesia, Africa):** As an example of innovation outside pharma, Indonesia's Ministry of Health launched a digital-health sandbox in 2023. This multi-stakeholder sandbox tested telemedicine and digital health services, generating recommendations for data governance. According to reports, the Indonesia sandbox "strengthened consumer protection and patient safety" and issued temporary regulations to allow innovators to test new tech <sup>[40]</sup> [thedataisphere.org](https://thedataisphere.org) <sup>[41]</sup> [thedataisphere.org](https://thedataisphere.org). Similarly, initiatives are exploring cross-border sandboxes (e.g. by the African CDC) to enable collaborative AI health research while respecting local data laws <sup>[42]</sup> [thedataisphere.org](https://thedataisphere.org).
- **Tackling Data Silos with Federated Learning:** Federated learning continues to gain traction. In January 2025, Owkin launched K1.0 Turbigo, an AI-powered operating system for drug discovery and diagnostics using federated learning with multimodal patient data, powering major pharmaceutical collaborations <sup>[43]</sup> [lifebit.ai](https://www.lifebit.ai). The MELLODDY project demonstrated FL's potential by aggregating 2.6 billion proprietary data points from 10 pharmaceutical companies for drug discovery <sup>[44]</sup> [springer.com](https://www.springer.com). The Federated Tumor Segmentation (FeTS) initiative improved glioma detection accuracy across 30 healthcare sites by harmonizing MRI data without sharing raw images <sup>[43]</sup> [lifebit.ai](https://www.lifebit.ai). Regulatory agencies including Swissmedic and the FDA have endorsed federated learning as an innovative method for data-centric collaboration without direct data sharing <sup>[45]</sup> [frontiersin.org](https://www.frontiersin.org). The global federated learning in healthcare market is expected to grow from \$30.62 million in 2024 to \$141.01 million by 2034, with pharmaceutical and biotechnology companies driving the fastest growth <sup>[46]</sup> [precedenceresearch.com](https://www.precedenceresearch.com).
- **AI Governance Initiatives:** Companies are creating internal AI governance frameworks. Industry groups have outlined guardrails (policies for fairness, explainability, data protection) to satisfy GxP needs <sup>[47]</sup> [ispe.org](https://www.ispe.org). The FDA CDER established an AI Council in 2024 to oversee AI-related activities <sup>[17]</sup> [fda.gov](https://www.fda.gov). In November 2025, the FDA launched an AI Benchbook and internal training courses to expedite future reviews by upskilling staff <sup>[18]</sup> [axis-intelligence.com](https://www.axis-intelligence.com). The EU AI Act's AI literacy requirements, effective February 2025, mandate that organizations ensure staff understand and manage AI-related risks <sup>[21]</sup> [pscsoftware.com](https://www.pscsoftware.com). These initiatives aim to address cultural and compliance barriers by defining roles, accountability, and controls for AI use.

## Emerging Trends in Overcoming Barriers

- Federated and Privacy-Preserving Learning:** Federated learning (FL) continues gaining traction as a way to leverage geographically or organizationally separated datasets without centralized sharing <sup>[48]</sup> [oecd.org](#). Advanced techniques like FedProx now help address data heterogeneity challenges, with well-designed federated models routinely achieving 95-98% of centralized model performance <sup>[43]</sup> [lifebit.ai](#). The integration of federated learning with blockchain technology is gaining prominence, providing an immutable ledger for transparent, auditable, and tamper-proof data exchanges <sup>[43]</sup> [lifebit.ai](#). Major players including GE Healthcare, Google, IBM, Microsoft, NVIDIA, Owkin, and Siemens Healthineers are driving innovation in this space <sup>[46]</sup> [precedenceresearch.com](#). Applications now span EHR-based hospitalization predictions, wearable ECG monitoring for arrhythmia detection, and Parkinson's disease progression tracking <sup>[43]</sup> [lifebit.ai](#).
- Regulatory Sandboxes and Pilot Zones:** Regulators are increasingly using *sandboxes* to learn about AI in life sciences. The EU AI Act (Art. 57) now **requires** each Member State to establish at least one AI regulatory sandbox by Aug 2026 [eur-lex.europa.eu](#). The UK's MHRA AI Airlock completed Phase 1 in April 2025 and is running Phase 2 through March 2026 with seven new technologies, informing a new regulatory framework expected in 2026 [gov.uk](#). The European Commission's November 2025 Digital Omnibus proposal aims to enable broader use of AI regulatory sandboxes and real-world testing <sup>[22]</sup> [dlapiper.com](#). Early reports suggest such sandboxes help identify practical issues and can accelerate market access for SMEs <sup>[49]</sup> [thedatasphere.org](#).
- AI Governance Frameworks:** Industry and standards bodies are converging on AI governance models tailored to life sciences. Frameworks (often patterned on existing quality systems) are being developed to address AI's ethical and technical risks. For example, the ISPE recommends formal policies on data privacy, fairness, explainability and security <sup>[19]</sup> [ispe.org](#) <sup>[50]</sup> [ispe.org](#). Pharmaceutical companies are also considering ISO/IEC standards (e.g. ISO 42001 for AI management systems) and guidance from NIST and EU. These governance efforts aim to institutionalize best practices, turning compliance requirements into structured processes.
- Collaboration and Data Sharing Initiatives:** Public-private partnerships and research consortia are forming to pool expertise and data. Examples include NIH's National AI Research Resource (NAIRR) to provide compute and data services, and multi-company alliances to develop AI for specific diseases. Such collaborations help overcome individual firm's data gaps and spread development costs, while engaging regulators early.
- Advances in Explainable AI (XAI) and Standards:** Technical progress in XAI tools (post-hoc explainers, inherently interpretable models) is helping address the "black box" barrier. Likewise, standard-setting organizations are working on benchmarks and validation criteria for medical AI. For instance, ISO and IEEE are drafting safety and process standards for medical AI/ML. Over time, these standards may streamline approval pathways by clarifying expectations.
- Regulatory Guidance Evolution:** As regulators gain experience, clearer guidance is emerging. The FDA's January 2025 draft guidance on AI in drug development, with final guidance expected Q2 2026, provides the first comprehensive framework for AI-supported regulatory submissions <sup>[15]</sup> [fda.gov](#). The January 2026 joint FDA-EMA guidance established 10 principles for responsible AI use in medicine development [ema.europa.eu](#). In the EU, the Commission's February 2026 stakeholder consultation will clarify high-risk AI classification for life sciences and healthcare <sup>[51]</sup> [cms-lawnow.com](#). These developments are reducing uncertainty and helping companies plan compliant AI strategies.

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## IntuitionLabs - Industry Leadership & Services

**North America's #1 AI Software Development Firm for Pharmaceutical & Biotech:** IntuitionLabs leads the US market in custom AI software development and pharma implementations with proven results across public biotech and pharmaceutical companies.

**Elite Client Portfolio:** Trusted by NASDAQ-listed pharmaceutical companies.

**Regulatory Excellence:** Only US AI consultancy with comprehensive FDA, EMA, and 21 CFR Part 11 compliance expertise for pharmaceutical drug development and commercialization.

**Founder Excellence:** Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

**Custom AI Software Development:** Build tailored pharmaceutical AI applications, custom CRMs, chatbots, and ERP systems with advanced analytics and regulatory compliance capabilities.

**Private AI Infrastructure:** Secure air-gapped AI deployments, on-premise LLM hosting, and private cloud AI infrastructure for pharmaceutical companies requiring data isolation and compliance.

**Document Processing Systems:** Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

**Custom CRM Development:** Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

**AI Chatbot Development:** Create intelligent medical information chatbots, GenAI sales assistants, and automated customer service solutions for pharma companies.

**Custom ERP Development:** Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

**Big Data & Analytics:** Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

**Dashboard & Visualization:** Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

**AI Consulting & Training:** Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at <https://intuitionlabs.ai/contact> for a consultation.

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