

Factors Hindering AI Adoption in Life Sciences: 2023-2025

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Barriers to AI Adoption in Life Sciences (2025)

Life sciences companies recognize that AI can dramatically accelerate research and development, improve patient care, and reduce costs aws.amazon.com/partners/genai/cio 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 2023–2025, and emerging solutions like federated learning, regulatory sandboxes, and AI governance frameworks.

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 [oecd.org ey.com](https://oecd.org/ey). As the OECD notes, “health data are sensitive and require handling with care through tight regulation” – making large-scale pooling difficult [oecd.org ey.com](https://oecd.org/ey). 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) 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 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 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 Life sciences regulators likewise emphasize transparency: new FDA draft guidance (Jan 2025) outlines risk-based frameworks for *credibility* of AI models in drug decision-making fda.gov.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 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 [ispe.org](#) [coherentsolutions.com](#). For example, factory-floor AI must interface with older equipment, necessitating robust MLOps and cybersecurity “guardrails” to meet [GxP](#) (Good Practice) requirements [ispe.org](#) [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. Companies face uncertainty as regulators catch up: for instance, the FDA recently released (Jan 2025) a draft guidance on using AI for [regulatory decision-making](#), proposing a “risk-based credibility assessment” for AI models supporting drug safety/efficacy [fda.gov](#) [fda.gov](#). Similarly, the EMA and ICH are considering AI in future guidelines. These evolving standards create compliance challenges – firms must demonstrate AI quality and transparency without clear precedents. The FDA reports a sharp rise in AI-related submissions (over 500 AI-enabled drug submissions by 2023 [fda.gov](#)), but there is still no fully harmonized path for AI-based products.
- **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 [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 [ispe.org](#) [coherentsolutions.com](#). For example, the ISPE recommends AI governance aligned with [GAMP 5](#), with processes for data integrity and risk management across AI development [ispe.org](#). Noncompliance can delay approvals or trigger enforcement.
- **Explainability and Risk Controls:** Both regulators and organizations are beginning to require explainability. The EU’s new AI Act (fully enacted Aug 2024) will mandate transparency measures and voluntary regulatory sandboxes [eur-lex.europa.eu](#). In the US, guidance and executive orders (e.g. White House AI EO 2023) push for AI safety, security, and fairness [lifescienceleader.com](#). Meeting these evolving requirements (explaining AI outputs, preventing bias) demands extra effort in model design and documentation. In practice, 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 [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 [capestart.com](https://www.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 [ey.com](https://www.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 [coherentsolutions.com](https://www.coherentsolutions.com) [lifescienceleader.com](https://www.lifescienceleader.com). But excessive anonymization can degrade AI model performance [oecd.org](https://www.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” [oecd.org](https://www.oecd.org) [oecd.org](https://www.oecd.org). For example, an OECD analysis notes that federated learning “enables researchers to gain insights collaboratively... without moving patient data beyond the firewalls” [oecd.org](https://www.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 [humanfactors.jmir.org](https://www.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” [humanfactors.jmir.org](https://www.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 [capestart.com](https://www.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 [capestart.com](https://www.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 [ispe.org](https://www.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 [oecd.org](https://www.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 [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 thedatasphere.org. Diagnostics companies must navigate both device rules and emerging AI-specific rules, making entry to market lengthy.

2023–2025 Case Studies and Examples

- **Early Adoption Successes:** A number of companies have publicly announced AI-driven gains. For instance, AstraZeneca reported that using BenevolentAI's platform let them advance *five drug targets* in under three years ey.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% ey.com. These examples show how AI can compress development timelines. Large pharma are also piloting AI analytics in manufacturing; Novartis, for example, uses AI to predict equipment failures and improve quality checks (reducing waste and errors) coherentsolutions.com coherentsolutions.com.
- **Regulatory Sandbox – UK AI Airlock:** In Spring 2024 the UK Medicines & Healthcare products Regulatory Agency (MHRA) launched **AI Airlock**, the first regulatory sandbox for AI as a Medical Device gov.uk thedatasphere.org. This pilot brought together NHS and industry to test real AI/diagnostic products under regulatory guidance. It aims to identify novel issues in certifying AI devices and to inform future policy. The AI Airlock is a partial solution to regulatory uncertainty, allowing limited experimental deployment under oversight.
- **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 thedatasphere.org thedatasphere.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 thedatasphere.org.

- **Tackling Data Silos with Federated Learning:** In 2023–2024 several consortia piloted federated learning to overcome privacy/data-sharing barriers. For example, a multi-center study on COVID-19 outcomes used federated models across hospitals in India, demonstrating accurate predictions without moving raw data [oecd.org](#). Such projects illustrate partial solutions: they tackle the barrier of distributed data ownership by updating models locally and sharing only weights or gradients, thereby maintaining patient privacy [oecd.org](#) [oecd.org](#).
- **AI Governance Initiatives:** Companies are also creating internal AI governance frameworks. For instance, industry groups have outlined guardrails (policies for fairness, explainability, data protection) to satisfy GxP needs [ispe.org](#) [ispe.org](#). Some pharma firms have formed AI steering committees (FDA CDER started an internal “AI Council” in 2024 [fda.gov](#)). These internal programs 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) is gaining traction as a way to leverage geographically or organizationally separated datasets without centralized sharing [oecd.org](#) [oecd.org](#). By keeping data in-place, FL reduces privacy hurdles and may encourage participation in AI studies. Researchers note that FL “will solve the problem of siloed datasets” by enabling secure cross-institution models [oecd.org](#). Privacy-enhancing technologies (homomorphic encryption, secure MPC) are being integrated into federated pipelines to bolster security [oecd.org](#) [oecd.org](#).
- **Regulatory Sandboxes and Pilot Zones:** As noted, 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](#). These sandbox programs (like MHRA’s AI Airlock) create “controlled experimentation” environments where developers and authorities can test innovative AI systems under relaxed constraints [eur-lex.europa.eu](#). Early reports suggest such sandboxes help identify practical issues (e.g. data usage rules, validation criteria) and can accelerate access to markets for SMEs [eur-lex.europa.eu](#) [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 [ispe.org](#) [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. FDA’s draft guidances (2025) and EMA/IMDRF discussions on AI for SaMD/diagnostics are examples. When final, these will reduce uncertainty. In parallel, patient-privacy rules are evolving (e.g. updated HIPAA, EU data acts) which, once settled, will help companies plan compliant data strategies.

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