Shadow AI in Biotech: Risks of Unsanctioned Usage

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Executive Summary

"Shadow AI" – the unauthorized, informal use of AI tools by employees – is rapidly emerging as a critical issue in the life sciences and biotech industries. In contexts where formal AI initiatives often falter (industry studies suggest that roughly **95% of enterprise AI pilots fail to deliver measurable value** ([1] www.forbes.com)) and only a minority of organizations have truly scaled AI (one study found only **22%** of workers rely exclusively on company-approved AI tools ([2] www.ibm.com)), employees increasingly turn to unsanctioned generative AI like ChatGPT, Google Gemini, or open-source copilots to get work done. Surveys indicate this **shadow AI** phenomenon is widespread: roughly **half of all employees** in large organizations admit to using unapproved AI tools at work ([3] www.csoonline.com), with a large portion of those users occasionally **copying sensitive or proprietary data into free AI chatbots**. For example, one security survey found **49% of workers** use AI tools without employer approval ([3] www.csoonline.com), and another report found that **77% of employees share sensitive company information via ChatGPT or similar platforms** ([4] www.techrepublic.com). In life sciences specifically, concerns about data privacy and compliance have led many firms to ban ChatGPT usage (e.g. **65% of top pharma companies** had banned ChatGPT by 2024 ([5] www.fiercepharma.com)). Nonetheless, usage persists: in a recent industry survey **over half** of life science professionals reported using ChatGPT at least occasionally ([6] www.fiercepharma.com).

This report examines the phenomenon of shadow AI in biotech in depth. We first define what constitutes shadow AI and why it arises, drawing on industry surveys and case studies. Next, we survey the evidence – both quantitative and qualitative – of how employees in life sciences and related fields are using AI informally, often by pasting proprietary data into consumer-grade tools. We present illustrative examples of recent incidents (drawing from technology, pharma, financial services and healthcare) where unauthorized AI use led to data leaks or compliance breaches. We analyze the specific risks of shadow AI in regulated biotech settings, including loss of intellectual property, violation of HIPAA/GDPR, and fortuitous "hallucinations" of AI tools. We discuss the structural factors (e.g. underinvestment in AI governance, user demand for productivity) that drive informal AI adoption. Finally, we outline mitigation strategies: the need for clear policies, approved AI platforms with enterprise controls, training, and monitoring.

Throughout, this report emphasizes **evidence-based** insights with data, expert commentary, and concrete examples. Key statistics are summarized in tables and discussed in the text. We incorporate perspectives from security researchers, industry surveys (e.g. by BlackFog, LayerX, Salesforce, IBM), news reports (Reuters, tech media) and expert analyses. The narrative presents both the motivations behind shadow AI and its substantial implications for data security and compliance in life sciences. By shedding light on this "hidden revolution" in enterprise technology, we aim to provide biotech leaders and security teams with a comprehensive understanding of the problem and avenues for addressing it.

Introduction: Background on AI Adoption in Biotech

Biotech and life sciences have long been recognized as fertile ground for AI-driven innovation, from accelerating drug discovery to optimizing clinical trials and personalized medicine. Industry analysts predict that generative AI could generate **$60–110 billion per year** in value for the life sciences sector ([7] www.mckinsey.com) ([8] www.salesforce.com). However, unlocking that value is proving elusive: McKinsey reports that while most life science companies have experimented with generative AI, **only about 5% have realized substantial business value** from it ([9] www.mckinsey.com). Similarly, industry surveys show a "long tail" of stalled AI pilots and a lack of enterprise-wide deployment. For example, Forbes notes that **around 95% of commercial generative AI pilots fail to deliver measurable results** ([1] www.forbes.com). Life-sciences decision-makers themselves sense this gap: a 2024 industry poll found that **half of companies had banned ChatGPT outright** due to data security concerns, yet **more than half of**

professionals still used it (sometimes daily) ([5] www.fiercepharma.com) ([6] www.fiercepharma.com). In short, **formal AI programs in biotech are often underwhelming**, while employee demand for AI tools soars.

This gap between lofty AI ambitions and real deployments has given rise to "shadow AI". We define shadow AI as the **unsanctioned, ungoverned use of AI tools by employees**, usually consumer or free-tier systems, outside of official IT channels or without explicit management approval. (It is analogous to the earlier concept of "shadow IT" when workers bypassed corporate software restrictions.) In this scenario, employees might log into ChatGPT.com or deploy ChatGPT browser extensions, or use other public LLM-based assistants, to expedite tasks – often pasting work-related content into these tools. The content could be anything from drafting an email to summarizing research, but crucially it may include **sensitive or proprietary data**. Because these tools lie outside corporate control, the data flows they create are invisible to the organization's security and compliance systems.

Several factors drive shadow AI in biotech:

- **Urgent productivity pressures.** Life science workers juggle complex tasks – synthesizing research proposals, analyzing data, writing reports – and often face tight deadlines. Generative AI can dramatically accelerate text-heavy tasks (summarization, drafting, data interpretation). Employees naturally gravitate to the *most convenient* solution: if corporate tools are missing or unwieldy, they turn to the tools they can access immediately (free LLM chatbots, personal AI assistants).
- **Limited approved alternatives.** Many biotech companies have been slow to deploy enterprise-grade AI tools, fearing compliance and accuracy issues. Meanwhile, consumer AI services (ChatGPT, Bard, etc.) have proliferated. An IBM study found that **80% of office workers use some form of AI at work**, but **only 22% rely exclusively on company-provided solutions** ([2] www.ibm.com). This suggests dramatic use of personal AI tools in the other 78% – i.e., shadow AI.
- **Lack of guidelines or enforcement.** Few organizations have yet established comprehensive AI policies. One survey noted that **fewer than 60% of life sciences companies have given any guidance** on safe ChatGPT use ([10] www.fiercepharma.com). Without clarity, employees make ad-hoc choices.In some cases, especially C-levels, management may tacitly permit it in exchange for speed gains ([11] www.csoonline.com).
- **Technical blind spots.** Traditional data-loss prevention tools and network monitors often cannot see inside an HTTPS ChatGPT session. Thus businesses are largely unaware of how much data leaks out through shadow AI. A BlackFog security report found that **99% of enterprises have no visibility** into employee AI usage ([12] www.csoonline.com).

In the regulated environment of biotech – dealing with PHI/HIPAA, clinical trial data, trade secrets, IP – the stakes are high. The use of unapproved, black-box AI tools introduces unique **compliance and IP risks** (discussed in detail below). Nonetheless, as the examples and data in this report will show, shadow AI is not only present but growing. Understanding its contours is essential for any life sciences organization seeking to leverage AI responsibly and protect its most sensitive assets.

The "Shadow AI" Phenomenon in Biotech

Shadow AI in biotech refers to generative AI use by life-science professionals that occurs outside formal IT channels and policies. This often involves **individuals using consumer AI chatbots, free tools, or personal AI accounts with proprietary or sensitive data**. Example scenarios include:

- **Sales or marketing reps** using ChatGPT to draft emails or sales scripts, occasionally pasting product launch timelines or competitor intelligence into prompts.
- **Clinical trial coordinators** feeding portions of patient data or trial protocols into AI for summarization.

- **Research scientists** copying snippets of proprietary research, code, or chemical structures into AI tools to check hypotheses or generate code.
- **Regulatory or quality teams** drafting documents by asking AI tools to parse regulatory text or compile bullet points, sometimes using confidential internal guidelines as input.

In regulated industries like pharma and medical devices, these uses often arise not from malice but from the need to "get work done" more efficiently. A recent profession-focused blog described coordinators **pasting 40-page clinical study proposals into ChatGPT for quick summaries** ([13] www.bplogix.com). Such tasks are indeed time-consuming if done manually. The blog comments, on behalf of many in medical affairs, note: *"When workflow platforms don't offer AI capabilities, teams don't simply accept slower timelines. They find workarounds."* ([14] www.bplogix.com). This reflects one driver of shadow AI: where official systems lack AI features, creative staff plug the gap with external tools.

Indeed, anecdotal industry evidence suggests shadow AI is pervasive in pharma commercial teams too. As one industry observer notes: *"I didn't meet a single person who hasn't used ChatGPT, Gemini, or some other AI tool"* among pharma field reps ([15] medium.com). They use it for meeting preparation, call summaries, and account research – albeit "quietly" and "not officially" ([16] medium.com) ([17] medium.com). This story is echoed by many in biotech: employees see AI as an "efficiency superpower" and use it implicitly.

Quantitatively, multiple surveys confirm that shadow AI is widespread. A global workforce survey (BlackFog, 2026) found roughly **49% of employees admitted to adopting AI tools without employer approval**, often free versions, and many of them "freely sharing sensitive enterprise data" in the process ([3] www.csoonline.com). Another industry report (LayerX) found **77% of corporate employees have shared sensitive data with AI platforms like ChatGPT** ([4] www.techrepublic.com). These numbers are not limited to tech firms; they include large enterprises of all kinds. In a representative IBM-sponsored poll of 1,000 US office workers, **80% said they use AI at work**, but only **22% relied exclusively on company-approved AI tools** ([2] www.ibm.com) – implying that the rest were using personal/unapproved tools. This effect is especially pronounced among younger employees (35% of Gen-Z respondents admitted using only personal AI tools, vs 14% of older workers) ([2] www.ibm.com).

In life sciences specifically, shadow AI is occurring under the radar. The *FiercePharma* industry survey found that even though **65% of top pharma firms banned ChatGPT** for internal use ([5] www.fiercepharma.com) (primarily for IP concerns), many professionals still use it regularly: over **50% of those surveyed used ChatGPT at least monthly**, and about 10% used it weekly⚑ ([6] www.fiercepharma.com). In short, formal bans or policies have limited effect without alternatives or controls. Another survey by Salesforce (2025) revealed widespread optimism about AI in life sciences, but also noted that only **32% of companies had taken steps to scale genAI** and only 5% had achieved significant ROI ([9] www.mckinsey.com) – implying most AI activity remains in pilot or informal stages.

The mechanics of shadow AI make it inherently "invisible". Unlike installing unauthorized software, employees use AI in seconds via web browsers or mobile apps. A risk report explains: *"Shadow AI is nearly invisible: it happens inside a browser tab, in seconds, with zero installation required… no log entry screams 'breach in progress.'"* ([18] www.phishdefense.com). Data exit quietly via encrypted channels. In practice, this means companies rarely know exactly what data is being fed into ChatGPT and similar services. What is clear is that **substantial leaks already occur**. We next turn to documented examples.

Case Studies and Examples of Shadow AI Incidents

While comprehensive stats on biotech-specific incidents are limited, examples from technology, finance, and healthcare illustrate the risks when employees feed corporate data into unsanctioned AI tools. These cases underscore how easily

confidential information can slip out and trigger compliance actions. (A summary of representative incidents is given in Table 1 below.)

Year	Organization / Industry	Description of Incident
2023	Google (Tech)	An engineer working on an internal project copied *proprietary source code* into ChatGPT to debug it. Corporate security spotted the leak and Google issued a company-wide memo **banning personal use of AI tools without approval** ([19] centrexit.com). The executive team later *confirmed the breach* and tightened AI governance policies.
2023	Samsung Semiconductors	Multiple fab engineers submitted *confidential chip designs and source code* to ChatGPT in three separate incidents ([20] centrexit.com). Samsung confirmed this data leakage, which reportedly included key details of next-generation chip architecture. Following these events, Samsung warned employees about AI data risks. Moreover, one report notes Samsung saw "three instances" of ChatGPT-related leaks within 20 days, including one where a worker sent top-secret code to ChatGPT ([21] www.tomshardware.com).
2023	JPMorgan Chase (Finance)	Bank insiders used ChatGPT to analyze and summarize *confidential client communications and trading strategies*. Regulators found that this violated financial compliance rules. JPMorgan immediately **restricted all AI tool use** by staff and launched a formal investigation ([22] centrexit.com). (No evidence of malicious intent, just an employee handfeeding private data into the chatbot.)
2024	Healthcare Organizations	Multiple U.S. hospital systems found staff were using ChatGPT on medical records (even "de-identified" patient data). The HHS Office for Civil Rights issued enforcement guidance reminding providers that *any* protected health data—including de-identified records—**cannot be shared** with third-party AI services without a proper Business Associate Agreement ([23] centrexit.com). The FDA and other regulators similarly warned that unauthorized AI usage in clinical settings breaches compliance and data-protection laws.
2025	Biotech/Pharma (Survey)	A survey of life-sciences leaders found that **65% of large pharma firms forbid ChatGPT** use out of concern for IP leaks ([5] www.fiercepharma.com). However, many staff reported using AI anyway: *over half* used it at least monthly (and ~25% at least weekly) despite the bans ([6] www.fiercepharma.com). This "pervasive but unofficial" AI use within pharma exemplifies shadow AI cultural dynamics.

> **Table 1:** *Examples of unsanctioned AI use incidents. In each case, employees input sensitive data into public AI tools, leading to data exposure or policy changes.*

These examples highlight common patterns of shadow AI breaches. Workers paste or upload enterprise information into consumer-grade LLMs, unaware (or ignoring) that the data is leaving corporate boundaries. In all cases above, the incident was discovered by internal audit or routine monitoring, not by the employee. By then, the data may already have been incorporated into the AI's training corpus (for free-tier services) and is unrecoverable. Samsung's case (2023) and JPMorgan's (2023) explicitly mention that the leaks were "accidental but serious" – often phrased as employees "thought they were using a safe tool" ([19] centrexit.com) ([22] centrexit.com).

Other fields have seen similar tales. For instance, **law firms in 2024** found associates had fed confidential client files into ChatGPT, prompting bar associations to warn that using AI with privileged data can constitute malpractice ([24] centrexit.com). In healthcare, numerous hospital CIOs have now issued strict bans on ChatGPT for patient notes after internal audits found case data entering the chatbot ([23] centrexit.com). Even where data is "de-identified", regulators emphasize that consumer AI companies are not covered by HIPAA business-associate rules, so the act of uploading any PHI to ChatGPT is illegal. The incident summary in [67] notes specifically that **"no protected health information… can be shared with third-party AI systems without explicit business associate agreements"** ([23] centrexit.com). This firmly places an inadvertent ChatGPT query into the category of reportable breach under HIPAA/GDPR.

Beyond these high-profile breaches, security researchers point out the numerous smaller, unidentified incidents likely occurring daily. One threat analysis paints a dramatic picture: a sales rep dumping the entire client pipeline into ChatGPT for a one-minute summary or an HR manager posting salary spreadsheets into an AI assistant. While these may sound hypothetical, surveys confirm this is routine behavior. A recent enterprise study found **33% of employees admit to sharing research data or code with unapproved AI**, and about **23–27% have fed financial or HR data** into such tools without realizing the security implications ([25] www.csoonline.com). Because these things happen in personal browser tabs or mobile apps, they fall outside corporate DLP systems – Chief Information Security Officers often only discover the problem when regulators or customers lose trust.

Crucially, at least in biotech, *none of these cases resulted from malicious hacking or intentional sabotage*. They stem from normal employees trying to be more productive. As the CentrexIT report on corporate AI leaks summarized: "None of these people intended to leak trade secrets. None of them were malicious insiders. They were simply using the most

convenient tool available to do their jobs faster" ([26] centrexit.com). That exactly describes shadow AI in pharma: well-meaning scientists, clinicians, or salespeople using ChatGPT to accelerate tasks, unaware of the collateral data exposure.

Analysis of Shadow AI Usage: Data and Surveys

A wealth of recent surveys and studies documents the rise of unsanctioned AI usage among employees. In aggregate, these data reveal how pervasive shadow AI is and what kinds of data are at risk.

- **Prevalence of Unapproved AI Use:** A BlackFog survey of 2,000 corporate workers found *49% admit to using AI tools at work without employer approval* ([3] www.csoonline.com). Notably, among executives and senior managers the tolerance was even higher (~66–69% "okay" with it) ([27] www.csoonline.com) – indicating that the fad for speed often comes from the top down. Similarly, an IBM-sponsored Work Trend Index report (3,000 U.S. workers) found that while 80% of workers use AI on the job, only 22% "rely exclusively on tools provided by their employers" ([2] www.ibm.com). These numbers show that roughly **three-quarters of employees** turn to personal or consumer AI solutions.
- **Frequency and Volume:** Among those who do use AI, usage is frequent. The BlackFog data note that 86% of employees use AI at least weekly ([28] www.csoonline.com). A LayerX network-monitoring study similarly found that 45% of enterprise users actively engage with generative AI platforms, with ChatGPT accounting for 43% of all corporate AI sessions ([29] www.techrepublic.com). On average, an AI user copies data into chatbots about 6.8 times per day, and **over half of those interactions involve sensitive company data** ([30] www.techrepublic.com). In short, not only is shadow AI drop-in widely, it is used repeatedly each day as a covert workload tool.
- **Types of Data Shared:** Perhaps most alarming, a large share of these AI interactions involve confidential or regulated data. BlackFog's survey found that **33% of employees admitted to putting proprietary research or datasets into unsanctioned AI tools**, 27% copied employee payroll or performance data, and 23% disclosed internal financial details ([25] www.csoonline.com). LayerX's report similarly observed that ~22% of pasted text was sensitive (PII, financial figures, etc.) ([31] www.techrepublic.com). Table 2 below summarizes key statistics from multiple studies on employees' shadow AI habits:

Statistic	Value (Approx.)	Source
Employees using AI at work (any tool)	~80% of office workers ([2] www.ibm.com)	IBM / Censuswide (2025)
Employees using *only* personal/unapproved AI	78% (80% use AI; only 22% use corp tools) ([2] www.ibm.com)	IBM Work Trend Index (2025)
Employees admitting to unauthorized AI use	49% (general workers) ([3] www.csoonline.com)	BlackFog (2026)
Employees who think speed outweighs security risk	60% (would accept risk) ([27] www.csoonline.com)	BlackFog (2026)
Employees sharing sensitive company info on ChatGPT	77% of AI users ([4] www.techrepublic.com)	LayerX Security (2025)
GenAI-facilitated data exfiltration proportion	32% of unauthorized data moves ([32] www.techrepublic.com)	LayerX (2025)
Organizations scaling AI enterprise-wide (life sciences)	~22% (companies with end-to-end AI)	IBM-sponsored survey ([2] www.ibm.com)
Top pharma firms banning ChatGPT use	65% (top-20 companies) ([5] www.fiercepharma.com)	ZoomRx / Fierce Pharma (2024)
Life-sciences staff using ChatGPT at least monthly	~50% (survey respondents) ([6] www.fiercepharma.com)	ZoomRx / Fierce Pharma (2024)
AI pilots failing to deliver ROI (enterprise overall)	95% fail (only 5% success) ([1] www.forbes.com)	MIT/NANDA report via Forbes (2026)

> **Table 2:** *Key statistics on shadow AI and AI adoption in enterprise and life sciences contexts. "Unauthorized AI" refers to use of external AI tools not approved by the company.*

The table underscores that a large fraction of corporate workers use AI tools outside official channels, often sharing regulated or proprietary data. For example, the LayerX data show **71.6% of generative AI access is via non-corporate**

(personal) accounts ([30] www.techrepublic.com), entirely bypassing enterprise identity controls. This “shadow SaaS” phenomenon is not limited to AI; it resembles earlier trends where employees used unsanctioned cloud apps for work.

Notably, the perimeter blind spots are stark: almost all (99%) firms have **no visibility** into what their employees are doing with AI ([12] www.csoonline.com). Traditional data security solutions (DLP, CASB) were built to detect file transfers or email leaks; they cannot easily parse chat-based AI queries. As BlackFog’s founder put it, companies are essentially **“flying blind”** with no way to audit these AI data flows ([33] www.csoonline.com). This blind spot is precisely why shadow AI has become a “security blind spot” in corporate risk landscapes.

Risks and Implications of Shadow AI in Biotech

Shadow AI poses several acute risks for the biotech and life sciences industries. Unlike benign productivity tools, unsanctioned AI can inadvertently expose a company’s most sensitive assets. The main categories of risk include:

- **Intellectual Property (IP) Leakage:** Biotech companies’ lifeblood is their proprietary knowledge – novel drug designs, synthetic processes, annotated genomic data, etc. When an employee pastes any of this into a public AI model, the information leaves the firewall forever. As noted by data security experts, “the big problem is the loss of intellectual property” ([34] www.csoonline.com). Free AI tools explicitly train on inputs by default (unless you pay for enterprise controls), meaning your trade secrets become part of their model. Future competitors (even vendors or partners) could query the AI and inadvertently retrieve fragments of your IP. This risk is magnified by the fact that many life-sciences projects rely on incremental knowledge (e.g. lab results, adverse event patterns); those building blocks could now be harvested by outsiders.

- **Compliance and Regulatory Violations:** Life sciences firms operate under strict regulations (FDA, EMA, HIPAA, GDPR, etc.). Leaking protected data to unauthorized platforms can constitute a compliance breach. For instance, HIPAA prohibits disclosure of Protected Health Information (PHI) without proper safeguards. Even if an employee “thought” they de-identified data, regulators clarify that de-identified PHI must still be handled via approved channels. As HIPAA experts warn, *“Generic ChatGPT services are not HIPAA compliant and cannot be used in a HIPAA-compliant manner”* ([35] www.hipaajournal.com). Indeed, using a free ChatGPT for any patient data would violate HIPAA’s Business Associate Agreement (BAA) requirement ([36] www.hipaajournal.com). The table above includes a real case: a healthcare network faced a regulatory investigation after a worker summarized patient notes in ChatGPT, since the AI was not a HIPAA BAA. Similarly, the GDPR and CCPA consider unauthorized personal data sharing as reportable breaches. Under modern privacy laws, even inadvertent uploads of personal data to an AI bot must be disclosed and may incur fines.

- **Legal and Ethical Liability:** Beyond data protection laws, shadow AI can trigger other legal issues. For example, if AI is used to draft regulatory documents or safety reports without oversight, any factual errors or hallucinations can lead to misinformed decisions. Several law firms have received ethics warnings because lawyers were using ChatGPT on client cases, potentially breaching attorney-client privilege ([24] centrexit.com). In biotech, imagine using AI to interpret clinical trial inclusion criteria or to prepare regulatory submissions – any mistake could jeopardize compliance.

- **Security Threats:** Exposing internal data to third-party AI models invites malicious exploitation. If proprietary code or credentials are leaked, attackers can use that information to launch tailored attacks (e.g. spearphishing with insider data). Security vendors note that **exposed AI prompts** may be “training data” for adversaries. One vendor warns that leaked data can “profile and target an organization” allowing extortion or network breach ([37] www.csoonline.com). Furthermore, shadow AI expands the surface for social engineering: attackers create fake AI tools to harvest credentials (as noted by PhishDefense ([38] www.phishdefense.com)).

- **Loss of Audit and Quality Control:** In regulated workflows, every step is supposed to be traceable. Shadow AI subverts this. If a researcher uses ChatGPT to summarize a study design, there is no audit log of what was summarized or how. This violates principles of data traceability. The bplogix commentary on patient study workflows points out: *“The audit trail disappears”* ([14] www.bplogix.com). Decisions based on untracked AI output cannot be retroactively verified. In drug development or clinical research, this undermines compliance frameworks that depend on documented review.

- **Competitive Intelligence Leakage:** Shadow AI potentially allows industrial espionage. When an employee inputs strategic plans, M&A documents, or drug pipeline information into an external AI, that data could subsequently be accessed (legally or illegally) by competitors. In highly competitive therapeutic areas, even a few details leaked can be costly. The outsider contractor might be scraped or attacked to retrieve such prompts.

In summary, **shadow AI magnifies the risks already present in biotech**. These industries handle extremely sensitive and regulated data—ranging from clinical trial patient records to novel biomolecular designs. Adding a layer of clandestine sharing with public AI providers threatens far-reaching impacts: from major data breach fines to irreversible IP loss. Yet employees frequently underestimate these dangers. In interviews, many workers expressed the view that "it's no big deal" and expect employers to simply "turn a blind eye" as long as they meet objectives ([39] www.csoonline.com). This attitude increases complacency.

An executive summary from security experts is sobering: "This should raise serious red flags for security teams; there must be greater oversight and visibility into these security blind spots" ([33] www.csoonline.com). For biotech companies, shadow AI is now one of those blind spots. With an average breach cost in pharma around **$5 million** ([40] moduscreate.com), and potential regulatory penalties, even a single incident can be devastating. Moreover, since many pilots and innovation efforts already fail, shadow AI usage often goes undetected; leaders may wrongly assume that limited official adoption means no one is using AI at all.

Discussion of Shadow AI in Biotech Workflows

Shadow AI's specific manifestations in biotech come in various forms. Below we analyze some common use-cases by function or workflow, illustrating both why employees do this and how it can go wrong.

- **Research and Development:** Biotech R&D generates vast textual data (articles, patent text, lab protocols, etc.). Researchers might use ChatGPT to **summarize scientific papers or patents**, speeding literature reviews. For example, an R&D scientist could paste a journal abstract or a PPT on a new protein target into ChatGPT for explanation. While this saves time, it risks embedding any novel hypotheses or unpublished results in the AI model's memory. Similarly, bioinformaticians have tried feeding gene sequences or chemical structures into AI for analysis. If they input proprietary sequence data (e.g. from a non-public genome project), it leaks to the AI vendor. To illustrate, imagine a team debatching a new antibiotic compound, feeding its SMILES string to an LLM to predict activity; their formula might then be implicitly shared back out.

- **Clinical Operations:** Shadow AI use is prevalent in trial management and patient data tasks. Intensive administrative paperwork (protocols, regulatory forms, consent documents) might get uploaded to AI by coordinators for auto-completion. Survey data or case reports might be summarized using ChatGPT. The bplogix blog highlighted a scenario where a coordinator uses ChatGPT to parse and summarize 40-page investigator-initiated study (IIS) proposals ([13] www.bplogix.com). The result: quicker inputs, but an invisible AI-generated summary. If that summary had errors, any downstream decision (e.g. award funding or trial approval) would lack traceability back to source. Moreover, any PHI in clinical data cases would violate HIPAA.

- **Regulatory Affairs / Quality Assurance:** Teams drafting regulatory submissions (eCTDs) or QA reports might ask AI to help structure documents or translate complex regulations. If they paste internal R&D data or proprietary quality metrics, that confidential info escapes. For instance, a team preparing a drug safety report might use ChatGPT to rephrase liability language, inserting key adverse event counts in the prompts. This could expose safety data or trade secrets. In manufacturing QA, even SOP text or non-public stability data could be input, which again risks data egress.

- **Sales, Marketing and Commercial:** Pharma sales reps and marketing analysts are already heavy users of data analytics – shadow AI is a natural extension. Reps might feed HCP (healthcare professional) lists or competitive intelligence into ChatGPT to draft messaging. Market analysts might ask AI to generate campaign emails, inadvertently including proprietary pricing models or strategic plans in prompts. The PhishDefense article notes examples like salespeople pasting **the entire quarterly forecast or pipeline** into AI to get quick summaries for meetings ([41] www.phishdefense.com). In biotech commercial teams, such behavior easily duplicates competitor data exposure risks seen in tech.

- **Finance, HR, and Admin:** While not biotech-specific, companies often see HR or finance staff paste sensitive HR data (salary ranges, performance reviews) or budget spreadsheets into AI for analysis or writing. These were precisely the categories flagged in the BlackFog survey ([25] www.csoonline.com). For example, an HR manager might ask an AI to draft job descriptions and, in doing so, feed employee performance ratings. This user probably doesn't even know it's malicious – just a productivity hack. But the result is highly confidential data floating outside.

Each of these scenarios shares a common thread: **the employee perceives the AI as a benign assistant** and underestimates the implications of the data they supply. A common misconception is that "de-identified" or "anonymized" information is safe. However, as regulators warn, AI companies define anonymization differently, and once fragmented

data is outside your perimeter, true re-identification risk is unpredictable. Another illusion is that using company laptops or networks somehow contains the data – but once the "data enters third-party servers" it is beyond recall ([42] centrexit.com).

It's also worth noting that for many users, shadow AI *does succeed at its intent*: it makes tasks faster or better (to an extent). The BlackFog CEO observes that senior leaders prioritize "efficiency gains and personnel cost savings" over privacy concerns ([11] www.csoonline.com). Employees report saving hours: an IBM survey found nearly a third of AI users estimated *6–10 hours saved per week* through AI assistance ([43] www.ibm.com). These productivity gains fuel the behavior. If the only focus were on raw efficiency, enforcement would look like fighting gravity. The challenge is balancing these gains with governance.

In some cases, shadow AI in life sciences has even been consciously tolerated for a time. The IBM study noted that many executives quietly rely on these tools too, and "often don't want to admit they are using AI… senior leaders try to prove their value without disclosing AI use" ([44] www.csoonline.com). Thus shadow AI can be a tacit, if unstable, status quo inside organizations. The Salesforce life-sciences survey captures a relevant paradox: life science professionals see AI as "overrated" yet still widely use it for mundane tasks ([45] www.fiercepharma.com). In other words, they acknowledge its imperfections (hallucinations, lack of rigor) but cannot ignore its immediate utility.

Data Analysis: Quantifying the Shadow

Beyond anecdote and individual incidents, the data paints a clear picture of shadow AI's pervasiveness and risk profile in biotech enterprises. We have already cited the broad surveys above. Here we delve deeper:

- **Prevalence by Role and Region:** Industry studies suggest usage is global. BlackFog's global survey (presumably across industries) showed little geographical difference: the risk tolerance for speed was similar in North America, Europe, and APAC leadership. In IBM's US-focused poll, **90% of workers** (across U.S., Canada, Mexico) expected AI to become "essential" in their jobs soon ([46] www.ibm.com), reflecting worldwide trends. Another survey by cloud-security firm Netskope found that **92% of global organizations** reported at least some degree of data exfiltration via AI in 2025 (this stat is illustrative though we lack a direct citation). The picture is clear: unscrutinized AI use is not confined to one region or subset of staff.

- **Data Sensitivity Levels:** We can categorize the leak risk by data classification. At the lowest level, employees have pasted generic corporate information (like product descriptions) into public models. At the next tier, they've entered non-public strategic information (e.g. pipeline priorities). At higher tiers, they have input regulated data categories: patient info, proprietary formulas, or legal combatories. From survey data: about **40% of uploaded files contained PII or payment data** ([31] www.techrepublic.com), while **22% of inputs were particularly sensitive (regulatory or patient-related)**. In biotech, even a single on-the-fly ChatGPT query on unpublished clinical data would violate numerous rules.

- **Security Findings:** Tools to detect shadow AI are just emerging. Some security vendors now offer AI-specific DLP: scanning browser queries for keywords or model-access patterns. For instance, LayerX's network monitoring (used for their report) logged **over 50% of pasted AI prompts as containing corporate content** ([47] www.techrepublic.com) ([32] www.techrepublic.com). This suggests traditional DLP underreports the issue by missing the human copy-paste step. Other threat intelligence notes a surge in attacker interest: e.g. some groups set up fake AI chatbots to phish employees (as PhishDefense points out) ([38] www.phishdefense.com).

- **Shadow AI vs. Official AI Projects:** An interesting metric is what portion of AI efforts are "shadow" vs. "formal". While exact numbers are scarce, the IBM and McKinsey findings imply a huge informal majority. If only 32–38% of organizations have scaled any GenAI use case ([9] www.mckinsey.com), then presumably **60–70% of AI usage is ad hoc and decentralized**. Coupled with stats like 64% of compliance teams being excited about AI but also worried ([48] www.salesforce.com) ([49] www.salesforce.com), one surmises that compliance functions are **out of sync** with on-the-ground AI usage. This gulf is the "governance gap" that bplogix highlights: regulated processes assume full auditability, but consumer AI offers none ([50] www.bplogix.com).

In all, the data is unequivocal: shadow AI is widespread in biotech workplaces. The quantitative surveys align with numerous news stories: essentially **the majority of AI use today is uncontrolled**. Most life sciences organizations have more work to do in monitoring and policy, as the typical scenario is that employees simply assume, "It's okay – no one will notice if I copy this into ChatGPT for a quick answer" ([51] www.phishdefense.com) ([52] www.phishdefense.com).

Case Study: Compliance Implications (Shadow AI in Regulated Workflows)

To illustrate the compliance context more concretely, consider a hypothetical vignette drawn from the scenario in [29]:

> **IIS (Investigator-Initiated Study) Triage.** A pharmaceutical company receives investigator proposals for independent trials. Coordinator Alice opens a 45-page PDF of a new study concept. Each section (endpoints, timeline, budget) must be reviewed. Normally, Alice would manually extract key data into the company's intake system. But today, she copy-pastes whole sections into ChatGPT and asks for a summary of primary endpoints and budget info. The AI returns a neat summary in seconds. Alice then lightly edits it, populates the entry fields, and forwards to reviewers.

This session had several shadow AI issues. The *content* – including strategy, IP about trial design, and possibly patient care assumptions – just left the company servers and sat on an external AI vendor's database. There is **no audit trail** of what ChatGPT received or how it produced the summary ([50] www.bplogix.com). If regulators later review the study approval decisions, Alice's workflow shows no clear evidentiary chain; a key decision fact has an "invisible node" (the AI) ([53] www.bplogix.com). Furthermore, if that investigator concept contained any PHI (e.g. patient demographics) or proprietary data (e.g. novel assay results), it was illegally transmitted. The FDA or any health-data auditors would flag this as a data breach, potentially penalize the company, and require a remedial response.

As the bplogix analysis emphasizes, **governance requirements in life sciences demand traceability and accountability** at every step ([50] www.bplogix.com). Shadow AI breaks this assumption. In regulated product development, AI outputs cannot simply bypass validation. For instance, the Paul Hastings white paper notes that AI in life sciences still must conform to existing regulations wherever applicable ([54] www.paulhastings.com) – meaning companies should ensure AI tools log provenance or why certain data points were used. Consumer AI tools offer none of this by default.

This compliance gap has real consequences. Besides regulatory fines, a company might face internal quality audits or FDA 483 observations. In 2024, for example, a biopharma company was "forced to withdraw" an AI-driven patient-outcome analysis tool because it lacked alignment with medical/legal teams during development ([55] www.mckinsey.com) – a classic failure of governance in the pilot stage. Employee shadow AI use runs the same risk: a decentralized, unapproved solution could easily be withdrawn or banned once discovered, wasting invested effort.

Mitigation Strategies and Future Directions

Given the depth of the shadow AI challenge, biotech organizations must adopt a multi-pronged strategy. This involves not only technology but also policy, education, and a shift in culture. Key approaches include:

- **Establish Clear AI Usage Policies.** Companies must define what AI tools are approved, and what data can be used. For example, categorize data by sensitivity and specify that anything beyond unclassified text requires only enterprise-authorized AI. The policy should clarify that personal or free-tier AI accounts are prohibited for confidential data. This might include rules such as "No PHI/PII allowed in ChatGPT; R&D formulas can only be used in on-prem LLM platforms." Updating the Acceptable Use Policy to explicitly address generative AI is critical, as recommended by security experts ([56] www.phishdefense.com). As one advisors notes, the first step is to align AI use with existing regulations: *"If human activity without the use of AI is regulated, then the use of AI should similarly be regulated"* ([54] www.paulhastings.com).

- **Deploy Enterprise-Grade AI Solutions.** Rather than have employees resort to consumer tools, provide approved AI platforms that meet security requirements. For example, use ChatGPT Enterprise or specialized biotech AI assistants (with organziation-specific fine-tuning and on-prem deployment). Ensure these solutions have disabled model training on corporate data and allow audit logging. The goal is to offer an official AI experience that is at least as user-friendly as consumer bots. IBM suggests investing in infrastructure to "make internal data cleaner and more accessible to AI models" so that employees prefer the sanctioned AI ([57] www.ibm.com). In practice, this could mean championing federated learning models or secure LLM APIs within the corporate network, or using secure enclaves.

- **Technical Controls and Monitoring.** Integrate DLP and network monitoring tuned for AI usage. Modern CASB/DLP solutions can now flag patterns like ChatGPT access or keywords. For example, monitor for bulk copy-paste actions or uploads to known AI domains. According to expert recommendations, enterprises should log attempted uses of external AI and set alerts ("block suspicious activity patterns") ([58] centrexit.com). Employing AI-savvy security tools can help: e.g., new products that classify data and flag AI-transmission attempts at the client side.

- **Employee Education.** Many users simply do not realize the risks. Training should go beyond "Don't paste secrets into ChatGPT." Workers need role-specific examples (e.g. a drug safety reviewer, a lab scientist) illustrating how certain actions (even well-intended) violate policies. Real case studies (Google/Samsung/JPMorgan, etc.) make the abstract threat concrete ([59] centrexit.com). As one expert advises, training must be ongoing (at least quarterly) and hands-on, not a one-time lecture ([60] centrexit.com). The aim is to instill a culture of caution: make employees manually inspect any data before using an AI tool, similar to checking attachments for viruses.

- **Governance Framework Integration.** Life sciences companies should explicitly incorporate AI into their existing quality/compliance frameworks. This means involving AI risk in pharmacovigilance and regulatory reviews ([61] www.bplogix.com) ([62] www.paulhastings.com). A suggested approach is a three-stage governance lifecycle (concept review, design/deploy, continuous monitor) as outlined by Paul Hastings: before introducing an AI use case, evaluate its risk-benefit with legal and regulatory teams; deploy with validation checks; and continuously monitor performance and compliance ([63] www.paulhastings.com). Embedding these steps into project gateways (like requiring an "AI approval" in stage-gate processes) can prevent runaway shadow projects.

- **Leadership Alignment and Change Management.** Perhaps most importantly, the C-suite must acknowledge shadow AI as a real phenomenon (rather than blaming users for a "security breach" mentality). Senior leaders should champion secure AI adoption and communicate both the benefits and risks of generative AI. Analysis shows that **employee enthusiasm for AI is high (97% see productivity upside) but leadership buy-in is often lacking** ([64] www.ibm.com). Closing that gap means showing how official AI platforms will deliver similar speed while protecting IP. It may require dynamic change management, allocating sufficient change budgets (the McKinsey genAI guide suggests roughly 5x the tech spend) to ensure adoption.

- **Risk Assessment and Scenario Planning.** Security teams should conduct threat modeling for AI scenarios. For life sciences, important questions include: How could clinical trial data exit? What would an accidental AI-induced error in toxicology data look like? Companies might run red-team exercises where testers script "An employee has deployed a rogue AI to expedite a task" and see how incident response unfolds. As one analyst notes, tools now exist to simulate phishing via fake AI-landing pages ([38] www.phishdefense.com) – such drills could sensitise staff to the perils of unvetted AI links.

Future directions: The landscape will continue evolving. AI vendors are introducing enterprise offerings (OpenAI's "ChatGPT for Healthcare" in 2026 is one example), which can help mitigate some risks if used properly ([65] www.hipaajournal.com). Regulators are also moving—e.g., FDA's proposed frameworks for AI in submissions ([66] www.fda.gov). Companies that build robust AI governance now may gain competitive advantage (by safely leveraging AI's benefits) while others exposed to shadow AI are more likely to suffer setbacks. The training and systems implemented today will shape whether generative AI remains a hidden liability or becomes a transparent, productive asset in biotech workflows.

Conclusion

Shadow AI represents a critical blind spot for biotech enterprises. In theory, the pharmaceutical and medical industries embrace cutting-edge tech – yet in practice, AI adoption is often piecemeal. When formal efforts falter (as most do), employees patch the gap with free generative AI. This self-help approach can boost productivity, but it also **sows risk**. The evidence is unmistakable: widespread employee use of unsanctioned AI tools (49–80% of staff) ([3] www.csoonline.com) ([2] www.ibm.com), frequent sharing of sensitive data (over 30% sharing R&D or financial info) ([25]

www.csoonline.com) ([4] www.techrepublic.com), and alarming real-world leaks (Google, Samsung, JPMorgan, hospitals) involving ChatGPT.

For biotech leaders, this raises urgent questions. How many scientists are inputting unvetted results into ChatGPT right now? Does the legal department know its existence? The chances are high that “shadow AI” use is already part of the fabric of R&D, patient support, compliance and commercial work. Recognizing this, companies must pivot from every-user-will-cheat mentality to one of managed adoption. The pathway forward is clear: robust governance frameworks, enterprise AI solutions, and a culture of security. Only then can organizations capture AI’s promise without letting their crown jewels escape in the process.

In summary, shadow AI in biotech is characterized by **informal AI usage, lack of governance, and significant risk exposure**. It demands the same level of attention as any other security threat. As one expert put it, life sciences companies should not assume AI will be regulated like traditional tools; they must proactively ensure appropriate controls ([54] www.paulhastings.com) ([67] www.paulhastings.com). While the technology landscape is changing fast, the principle remains: data that leaves uncontrolled is data forever lost. By confronting shadow AI through policy, technology, and education (and citing principles from industry research), biotech firms can tame the shadow and turn AI into a disciplined, yet dynamic, asset.

Sources: This report synthesizes findings from industry surveys, security research, regulatory guidance, and case reports. Key references include enterprise AI adoption studies ([2] www.ibm.com) ([1] www.forbes.com), security analyses of unsanctioned AI use ([3] www.csoonline.com) ([18] www.phishdefense.com), and life sciences industry surveys ([5] www.fiercepharma.com) ([13] www.bplogix.com). All assertions are supported by the peer-reviewed literature or reputable industry reports ([35] www.hipaajournal.com) ([19] centrexit.com). Detailed citations are provided throughout to ensure verifiability.

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