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Agentic AI in Pharma: Scaling from Pilot to Production

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Executive Summary

Agentic AI uses **goal-directed systems that dynamically control their processes and tool use**, implemented through **single-agent or multi-agent designs** (Anthropic; Microsoft; Berkeley CLTC). These goal-driven AI “agents” decompose high-level objectives into coordinated subtasks, integrating data from multiple sources, drafting and revising documents, and alerting or escalating to human experts as needed (www.pharmtech.com) (pharmaconsulting.ai). In R&D and clinical development, the technology promises to greatly accelerate knowledge work. For example, one agentic AI proof-of-concept platform for early-stage research (biomarker discovery) achieved **~60% reductions in literature review time** and **3× faster assay report drafting**, all with full audit trails (www.factspan.com). In clinical development, Medable describes Agent Studio as a no-code builder that lets clinical teams configure AI agents (Medable). In manufacturing and quality operations, Sakara describes agents assembling data, performing analysis, and producing drafts for deviation investigations (Sakara Digital).

McKinsey reported in June 2025 that **more than 80% of companies reported no material contribution to earnings from their generative-AI initiatives** (McKinsey). This enterprise-benefit finding is not a pharmaceutical-pilot failure rate. Common failure points include fragmented data environments, lack of integration with legacy systems, insufficient user adoption, and regulatory hurdles. As a life-sciences executive put it, “Even a flawless AI model fails if it’s not adopted,” noting that AI tools often introduce *friction* into established workflows and demand new governance processes (www.linkedin.com) (www.mckinsey.com). Crucially, agentic systems raise new trust and safety concerns: increased autonomy can lead to unintended behaviors (e.g. self-replication or resistance to shutdown) if not properly constrained (cltc.berkeley.edu).

Regulators are taking note. In **January 2025** the FDA released draft guidance for AI in drug and biologic submissions, acknowledging AI’s “transformative potential” for clinical research while stressing a risk-based oversight framework (www.fda.gov). As of 15 October 2026, the EU’s AI Act had entered into force on **1 August 2024** and become generally applicable on **2 August 2026**, with exceptions (European Commission). International work (e.g. FDA–EMA principles, CIOMS frameworks) is underway to align innovation with safety and compliance.

Moving “from proof-of-concept to production” requires addressing these challenges. Life-sciences firms are investing in data infrastructure, model validation, and cross-functional change management. McKinsey’s January 2024 analysis modeled **$60–110 billion in potential annual value across the pharmaceutical industry value chain from generative AI** (McKinsey). This is an economic opportunity estimate, rather than measured ROI from agentic deployments. Skilled staff are retraining to oversee AI agents rather than execute routine tasks, shifting human focus to higher-value problem-solving (www.mckinsey.com). As one industry leader noted, pharma R&D budgets are beginning to **pivot from wet labs to AI supercomputing** (www.axios.com). Looking forward, integration of agentic AI with lab automation and digital twins could enable “self-driving” laboratories that iteratively design and execute experiments, ultimately accelerating innovation while preserving human oversight (www.sciencedirect.com) (cltc.berkeley.edu).

Table – Key Agentic AI Use-Cases in Pharma (2026):

Use Case / Domain	Agentic AI Approach	Reported Impact / Benefits	References
Hypothesis generation (Early R&D)	Multi-agent platform orchestrates literature search, data curation, and draft experimental plans (pharmaconsulting.ai)	~60% reduction in literature-review and drafting time; 3× faster structured report creation with embedded citations (www.factspan.com)	See linked Factspan case study in this row
Clinical Trial Operations	AI/ML-assisted trial-site selection	McKinsey describes AI-driven site selection as outperforming traditional methods; this is not a measured agentic-system result.	McKinsey: AI/ML in clinical development
Quality / Deviation Management	Sakara describes agents assembling data, performing analysis, and producing investigation drafts	Workflow description	Sakara Digital
Regulatory Documentation	Agents coordinate global data and draft regulatory submissions (dossiers, SOPs) with audit trails	Early experiments show faster draft generation and improved consistency (quantified data emerging)	

Use Case / Domain	Agentic AI Approach	Reported Impact / Benefits	References
Pharmacovigilance & Safety	Agents triage adverse-event reports, analyze literature, flag safety signals	Improved throughput of case intake and signal detection (largely in development)	

1. Introduction and Background

The pharmaceutical and biotechnology (life-sciences) industries have always been data- and research-intensive. Over the past few decades, computational methods have gradually augmented human expertise in drug discovery, clinical development, regulatory affairs, manufacturing, and safety monitoring. Early AI work (1980s–2000s) focused on rule-based expert systems and then machine learning models for specific tasks (e.g. molecular docking, image analysis). In recent years, **deep learning** breakthroughs (e.g. AlphaFold) have demonstrated that AI can achieve remarkable accuracy on complex scientific problems. For example, DeepMind's AlphaFold2 in 2020 was able to predict 3D protein structures with atomic precision, vastly reducing the time and cost of structural biology (www.nature.com). Similarly, **foundation models** – large neural networks pre-trained on massive data – have proliferated: as of 2025, **over 200 such models have been published in drug discovery and pharma R&D** (www.sciencedirect.com). These models have been applied to genomics, target identification, molecule design, and other tasks, offering generative capabilities far beyond narrow algorithms.

In 2022–2023, **Generative AI** (GenAI) exploded into public view with (for example) ChatGPT and other foundation-language models. These systems can synthesize text, code, images, and more by learning patterns from vast datasets. In pharma, GenAI is already widely used for **information processing tasks**: preparing regulatory documents, summarizing literature, drafting clinical reports, and extracting insights from databases (www.pharmtech.com). For instance, ChatGPT-like systems have been used to auto-populate draft marketing authorization applications, to label and sort adverse event narratives, and to answer research queries (www.pharmtech.com) (apnews.com). These applications treat AI as a "cognitive assistant" or advanced search tool. Generative AI has yielded gains in efficiency: pharma firms report accelerated regulatory submissions, faster case processing in pharmacovigilance, and more streamlined R&D workflows when AI augments human work.

Agentic AI uses generative models within systems that are given an explicit goal and then autonomously plan and execute a sequence of operations to achieve it. In other words, rather than merely **answering queries**, agentic AI systems **receive objectives** (e.g. "prepare a complete clinical study report draft for a new diabetes drug") and may then invoke multiple AI "agents" – each specialized in facts retrieval, reasoning, data analysis or document drafting – to carry out all required steps. In this multi-agent design, the specialist agents are orchestrated by a "super-agent" that monitors progress, handles exceptions, and adapts plans on the fly (www.pharmtech.com) (www.mckinsey.com). Single-agent designs are also possible (Microsoft).

Conceptually, an AI *agent* can be viewed as a **structured helper** that possesses memory, reasoning, and action capabilities within a particular domain (pharmaconsulting.ai) (www.mckinsey.com). For example, in a regulated pharma workflow, one agent might be responsible for breaking a goal into a step-by-step plan, another agent for retrieving relevant validated data sources, another for drafting and comparing document excerpts, and another for routing tasks to the appropriate human reviewer with deadlines and evidence

attached (pharmaconsulting.ai). The agents operate under defined superivised autonomy: they work largely independently but “consult” human overseers when encountering critical decisions or compliance issues (www.mckinsey.com) (cltc.berkeley.edu). This **human-in-the-loop design** is essential, especially in life sciences, where every decision must remain auditable and defensible. As one McKinsey analysis notes, “Because the life sciences industry is strictly regulated, agents must consult humans before making important decisions or performing major tasks” – enterprises set the guardrails around the agents’ autonomy (www.mckinsey.com).

Agentic AI can use language models to dynamically direct processes and tool use (Anthropic). This autonomy enables agents to handle **multi-step, conditional workflows** across multiple systems. For example, instead of simply answering “Which batch deviated?” an agentic AI could detect an anomaly in manufacturing data, retrieve all relevant batch dossiers, run simulations against historical norms, draft a complete deviation report, and route it to the quality assurance manager — all without explicit prompts at each stage (sakaradigital.com). In short, agentic AI can act as an “operational participant”, executing complex tasks end-to-end rather than just providing best-guess inputs (sakaradigital.com) (www.pharmtech.com).

The life sciences industry is particularly well-suited to benefit from agentic AI. It is **outcome-critical and data-rich** (e.g. genomic databases, clinical trial records, adverse event registries), yet also highly **process-driven** and complex. Recent industry analyses highlight that agentic AI’s capabilities map well onto pharma needs: multi-agent collaboration can greatly enhance scientific discovery, automate repetitive documentation, and streamline quality/regulatory processes (www.pharmtech.com). By autonomously reasoning and synthesizing knowledge, agentic systems promise to reduce bottlenecks across drug discovery, clinical operations, manufacturing, and post-market surveillance (www.pharmtech.com) (www.sciencedirect.com).

However, transforming these promises into routine practice is nontrivial. The next sections examine the state of agentic AI in pharma (as of 2026), including key applications, implementation barriers, data-driven evidence of impact, and the broader implications for the industry.

2. Defining Agentic AI and Differentiators

Agentic intelligence refers to **autonomous, goal-oriented AI systems** capable of planning, acting, and learning with minimal direct supervision (www.mckinsey.com) (www.pharmtech.com). An *AI agent* perceives its environment (data sources, software systems, possibly even physical institutions) and determines actions to achieve a specified objective. Such agents use a mix of machine learning (e.g. LLMs) and rule-based logic, equipped with memory mechanisms to keep track of progress and context over time and across steps (www.mckinsey.com) (www.pharmtech.com). One possible architecture is a **hierarchy of agents**: specialized agents (e.g. literature-review agent, document-drafting agent, data-extraction agent) and a coordinating orchestrator. Single-agent designs are another option (Microsoft). Given a goal (like “complete a clinical study report” or “analyze quality deviations”), the orchestrator decomposes it into tasks, assigns subtasks to the specialist agents, monitors their execution, and handles any exceptions (such as missing data or conflicting results). The orchestrator may adjust plans in-flight, akin to how a project manager reallocates resources or revises timelines as work unfolds (www.pharmtech.com) (sakaradigital.com).

An **isolated model call** uses the context supplied with that request. A conversational application can retain earlier turns and supply them on subsequent calls: for example, Anthropic's Messages API is stateless while supporting conversations built up over time (Claude API documentation). For agents, the distinguishing feature is that models dynamically direct their processes and tool use (Anthropic).

Figure 1 (below) compares some key attributes:

Attribute	Generative AI (isolated model call)	Agentic AI (AI Agents)
Interaction	Responds to one-time prompts or queries (www.pharmtech.com)	Accepts high-level goals and plans multi-step workflows (www.pharmtech.com) (sakaradigital.com)
State/Memory	Uses the context supplied in the request; an application can include earlier conversation turns (Claude API documentation)	Maintains context and memory across steps (www.mckinsey.com)
Autonomy	Tools invoke model; requires user to manage flow	Agents decide next actions, can invoke tools dynamically (www.pharmtech.com)
Task Scope	Typically single task (e.g. translate text, summarize)	Can handle complex, branched processes (e.g. issue a report) (www.pharmtech.com)
Human Role	User initiates each query and guidance	Human oversees, validates decisions, intervenes as needed (www.mckinsey.com)
Adaptability	Does not modify behavior mid-task unless re-prompted	Continuously adapts plan to new information, exceptions (sakaradigital.com)

Overall, agentic AI in pharma represents an **architectural evolution** rather than a mere algorithmic tweak (sakaradigital.com). It builds on the underlying AI models (LLMs, vision models, knowledge graphs) but adds planning engines, integration layers, and human-in-the-loop management. Importantly, in regulated environments like pharma, agentic systems must be **implicitly governable**: all actions and decisions are logged, traceable, and can be overruled. As McKinsey notes, in life sciences "AI agents…should always have mechanisms to consult and defer to humans on critical tasks," with corporate governance defining the guardrails (www.mckinsey.com) (www.linkedin.com).

In summary, agentic AI "transforms AI's role from tool to coworker" (www.mckinsey.com). Agentic systems may use one agent or coordinate multiple agents, depending on the application (Microsoft).

3. Evolution of AI in Pharma: From Proof-of-Concept to Agentic Systems

3.1 Historical Context of AI in Pharma

Artificial intelligence techniques have been gradually adopted in pharmaceutical R&D and operations over many years. Early initiatives in the 1990s–2000s focused on automating routine tasks: knowledge-based expert systems for diagnostics, statistical models for compound screening, and data-mining of electronic

health records (EHRs). These systems, often built internally or with cloud tools, showed promise but were largely siloed in specific departments (e.g. a quality control application or a clinical data trend analysis). Over time, machine learning and deep learning broadened capabilities, allowing image interpretation, genomic analysis, and predictive modeling. Landmark successes (e.g. identifying drug targets from multi-omic data, optimizing chemical syntheses) built confidence that AI could enhance pharma productivity. Nevertheless, adoption typically stalled at pilot scale due to data integration and regulatory compliance issues (www.linkedin.com) (www.mckinsey.com).

The launch of **AI Chatbots and LLMs in 2022** marked a turning point. Models like GPT-3/4 demonstrated general reasoning and language skills, prompting pharma companies to experiment heavily with generative applications. As one PharmTech review noted, GenAI "proved a disruptive catalyst for whole industries," enabling rapid drafting of regulatory documents, summarization of literature, and natural-language data queries (www.pharmtech.com). Pharma firms tried dozens of pilots: for instance, using ChatGPT to answer regulatory questions or to translate medical language. These generative tools *reclaimed many hours of expert labor* by accelerating writing and information retrieval tasks (www.pharmtech.com). Yet, most such pilots remained point solutions, and far from fully automated production.

Meanwhile, investments in foundational AI research were mounting. In drug discovery, there was a "phenomenal" growth in foundation models. A 2025 review reports that **since 2022, over 200 distinct foundation models** tailored to pharma applications have been developed (www.sciencedirect.com). These ranged from protein-language models and large chemistry networks to multi-modal biomedical models (www.sciencedirect.com). By leveraging these models, companies aimed to improve target identification, predict molecular properties, and accelerate molecule design. For example, recent work shows applications of AI agents that can autonomously search literature, design virtual screening pipelines, or generate hypotheses about biological pathways (www.sciencedirect.com) (medium.com).

In late 2024 and into 2025, the idea of **integrating multiple AI tools into autonomous agents** began to coalesce. Publicly, companies like Google introduced research projects (e.g. the "AI Co-Scientist") demonstrating how interconnected AI models could propose experiments (www.pharmtech.com). Startups and pharma partnerships emerged: for instance, in January 2026 Eli Lilly and NVIDIA announced an AI co-innovation lab, with a combined commitment of up to $1 billion over five years for talent, infrastructure and compute (Lilly announcement). Industry analysts simultaneously flagged that enterprises were moving from GenAI curiosities toward true agentic systems: forecasts suggested that by 2027 roughly half of organizations using gen-AI would implement agentic solutions (www.mckinsey.com) (sakaradigital.com). In short, by 2026 the **pilot phase** of AI in pharma was giving way to a phase focused on scaled, integrated deployments – especially using multi-agent architectures.

Figure 2 (below) illustrates this trajectory: AI in pharma has evolved from **simple automation** (e.g. rule-based checks) → **machine learning assistance** (e.g. predictive models for specific tasks) → **generative AI augmentation** (chatbots, summarization tools) → **agentic AI orchestration** (goal-driven autonomous workflows) (www.pharmtech.com). Each stage built on the previous one, but agentic AI is unique in **enabling cross-functional, end-to-end autonomy**.

3.2 Proof-of-Concepts and Early Trials

By 2026, many agentic AI initiatives in pharma are still at the **proof-of-concept (PoC) or pilot stage**, but momentum is building rapidly. Tens of pilot projects have been reported or announced across major pharmas and CROs. Notable examples include:

- **Hypothesis-generation engines**: Several companies have partnered with AI vendors to create PoCs where an agent ingests vast scientific literature and internal data to propose experiment designs. For instance, a global biopharma teamed with Factspan to build an **agentic hypothesis generator** for biomarker discovery (www.factspan.com). This multi-agent prototype combined large language models with domain-specific knowledge graphs. In trials, it delivered **dramatic speed-ups** in literature analysis (~60% less human time) and generated structured reports (3× faster) with full traceability of sources (www.factspan.com). The reduction in manual drafting led medical scientists to focus on critical interpretation and validation rather than clerical work. (See Case Study #1 below.)
- **Clinical trial acceleration**: Agentic AI has been piloted in trial management to reduce manual monitoring. Medable and other tech-CDMOs have experimented with AI assistants that autonomously track enrollment rates, query missing data, and alert coordinators. One pharmavoice article describes how new “AI agents” can not only report on trial metrics but **take corrective actions** (e.g. reallocating enrollment efforts) without waiting for human commands (www.pharmavoice.com). Formation Bio says it has begun incorporating LLMs and AI models into its work (Formation Bio).
- **Regulatory compliance and documentation**: Large pharmas have run pilots where AI agents assemble parts of regulatory submissions. These systems integrate internal study archives, external guidelines, and real-time inputs to fill draft applications. For example, an agent might autonomously compile the initial draft of a product-change impact analysis by pulling from historical data and EMA guidelines, then flag uncertainties for human review. Though largely PoC, such efforts demonstrate reduced form-filling and cross-team coordination effort.

While impressive, **none** of these agents (as of early 2026) is yet a fully validated production system. In each case, the agentic AI operates under controlled conditions, on defined datasets, and with humans always on standby to correct errors. However, these PoCs do offer concrete evidence that agentic workflows can deliver **measurable efficiency gains**. McKinsey’s agentic-AI analysis describes potential capacity improvements at the task level; these may represent fractions of employees’ time (McKinsey).

4. Applications of Agentic AI in Pharma

Agentic AI’s design allows it to be applied across virtually all functional domains of a pharmaceutical company. We categorize its most mature and promising applications as follows:

4.1 Drug Discovery and R&D

The **front end of the R&D pipeline** is rich with data and hypothesis-driven tasks – an ideal testbed for agentic AI. Key opportunities include:

- **Literature review and hypothesis generation**: Defining research hypotheses often begins with extensive review of scientific papers, patents, and databases. Agentic AI can automate this: an orchestrator agent can be given the goal “Find novel targets related to chronic inflammation.” It then tasks a literature-search agent to scan PubMed, a data-extraction agent to pull key experimental findings, and a reasoning agent to synthesize trends. Such agents can draft suggested hypotheses or experimental plans, complete with citations. In practice, pilot platforms have shown they can **search weeks of literature in minutes**, producing organized insights. For instance, the Factspan case study demonstrated that scientists achieved a **~60% reduction in literature-sourcing time** when using an agentic system (www.factspan.com).
- **Molecular design and optimization**: After targets are identified, designing or optimizing lead compounds is critical. Agentic AI can potentially drive **autonomous lead optimization cycles**. For example, an agent tasked with finding improved analogs of a molecule might (a) scan chemical databases for similar structures, (b) use predictive models to score their efficacy and safety, (c) design new variants, and (d) propose focus compounds to chemists. Each cycle could be faster and more systematic than manual brainstorming. Early pilots (though still experimental) suggest that agents linking generative chemistry models with predictive filters can propose high-quality candidate molecules in a fraction of the time (medium.com) (www.sciencedirect.com).
- **Biological data analysis**: High-throughput experiments generate massive datasets (transcriptomics, proteomics, high-content screening). An agentic AI can autonomously analyze these multi-omic data to identify signal. For example, agents can autonomously run clustering algorithms, integrate clinical metadata, and draft interpretations of gene expression signatures. The agents can learn iteratively: if initial analyses are inconclusive, they might adjust parameters or request additional data querying. While still experimental, such end-to-end analytics have the potential to speed up target validation and biomarker discovery.

Case Study 1 – Hypothesis Generation Platform (Factspan):

A global biopharmaceutical company piloted an agentic AI platform to accelerate early R&D. Given a research goal (e.g. “identify potential biomarkers for kidney disease”), the platform deployed multiple specialized agents: a literature-mining agent to gather relevant publications, a domain-knowledge agent to cross-reference gene/protein databases, and a report-generation agent. During the PoC, biologists reported dramatic efficiency gains: the system reduced their literature review and drafting time by ~60%, and produced structured assay design reports three times faster than traditional methods (www.factspan.com). Importantly, each output included embedded traceability (every suggestion had a linked source), making the results immediately “audit-ready” for regulatory science purposes. Biologists then spent more effort validating the hypotheses rather than on manual data assembly. This example illustrates how agentic AI can augment, not replace, expert researchers by removing tedious tasks (findings backed by (www.factspan.com)).

4.2 Clinical Development and Trials

Clinical trial execution is notoriously slow and expensive. Agentic AI holds promise to **streamline trial management** by automating many administrative and monitoring tasks:

- **Site selection and patient matching**: Agents can ingest trial protocols and electronic health record (EHR) data to autonomously identify suitable trial sites and patient cohorts. For example, given a rare-disease trial plan, agents scour global EHR databases, apply inclusion/exclusion criteria, and generate ranked lists of candidate sites and patients. They can also monitor recruitment status in real time, alerting human teams when enrollment lags.
- **Data monitoring and compliance**: Traditional monitoring requires site visits and spreadsheet checks. Agentic AI can continuously monitor incoming data streams (eCRF entries, lab reports) for anomalies or missing data. If deviations occur (e.g. inconsistent lab values), an agent could autonomously query the site, request clarifications, or adjust data-collection prompts. As noted in Pharmacovigilance AI reports and Medable's announcements, agents are being developed to "navigate tedious tasks" such as chasing down site paperwork (www.pharmavoice.com). Early trials indicate agents can handle many monitoring queries without human prompting, freeing monitors to focus on oversight.
- **Regulatory document automation**: Preparing the vast documentation for trial filings (e.g. investigator brochures, informed consent forms) is labor-intensive. Agentic systems can assemble templates, auto-fill sections from updated protocols, and compile risk assessments. For instance, an agent might automatically draft the initial clinical trial protocol by pulling relevant sections from disease vocabularies and regulatory guidelines, then route it to medical writers for review. While still nascent, this could shave weeks off study start-up timelines.
- **Clinical trial monitoring**: Medable introduced CRA Agent, an agent running on Agent Studio specifically designed for clinical trial monitoring (Medable).

According to an industry survey cited by *PharmaVoice*, about **70% of pharma executives now see AI as an immediate priority** in areas including trial operations (www.pharmavoice.com). External analyses (McKinsey) have found that companies deploying AI/ML in clinical studies can **increase patient enrollment by ~20%** (www.pharmavoice.com). Agentic AI is poised to amplify these effects: by automating novel tasks (not just analytics) and enabling faster decision loops, it may significantly shorten trial timelines. For example, Formation Bio reports incorporating LLMs and AI models into its work (Formation Bio).

Importantly, **clinical stakeholders emphasize careful implementation**: pharmacists and investigators stress that any autonomous agent in trials must always allow human validation and follow strict GCP principles. In practice, current clinical AI pilots keep physicians in ultimate control: agents provide analysis and alerts, but physicians authorize any protocol changes. Over time, however, agents are expected to handle increasingly sophisticated coordination of complex trials (e.g. decentralized virtual trials) under oversight.

4.3 Manufacturing, Supply Chain, and Quality Operations

Manufacturing of pharmaceuticals involves intricate processes and strict quality controls. Agentic AI can be applied to **optimize production and ensure compliance**:

- **Production planning and execution**: Agents can autonomously plan manufacturing runs. For instance, given a target product and timeline, an agent could coordinate raw material procurement, monitor inventory levels in real time, adjust production schedules to avoid delays, and ensure cross-facility

coordination. In one proof-of-concept, an agent monitored sensor data from a fermentation batch, detected early deviations, and autonomously recalibrated control systems to prevent batch loss. (Though still experimental, such uses hint at higher overall throughput and lower scrap rates.)

- **Quality control and deviation management**: Agents can scan in-process quality data (e.g. NIR spectroscopy, HPLC results) to flag anomalies. When a deviation occurs, an agent can immediately retrieve the relevant batch history, compare to historical deviations, and draft a complete investigation report with suggested root causes and corrective actions. Sakara describes agents assembling data, performing analysis, and producing draft investigation reports (Sakara Digital).
- **Document management and SOP generation**: Updating standard operating procedures (SOPs) and quality manuals is a recurring overhead. Agents can help auto-generate SOP drafts by pulling regulatory requirements and process changes, then circulate them for approvals. They can also manage training schedules by detecting which employees need retraining on new processes, sending reminders automatically.
- **Supply-chain resilience**: Though less explored in public literature, agentic AI could manage global pharma supply chains. By ingesting global demand forecasts, raw material availability data, and manufacturing constraints, an agent can re-plan logistics dynamically. Early-stage projects (often in consumer industries, but increasingly in pharma) suggest agents could mitigate shortages by autonomously reserving capacity at alternate sites when one plant goes offline.

The net effect is to make pharma manufacturing more **reactive and agile**. As one industry analysis observes, the move from GenAI assistance to agentic orchestration in 2026 is “structurally different” for regulated industries (sakaradigital.com). An agentic AI that, for example, detects an out-of-spec result and then automatically drafts a full investigation report is “fundamentally” more capable than a chatbot that merely drafts a deviation narrative (sakaradigital.com). The transition from using AI as a “productivity layer” to an “operational participant” could yield step-changes in output and quality consistency.

4.4 Safety Monitoring and Pharmacovigilance

After a drug is on the market, monitoring its safety becomes paramount. AI (so far mostly narrow models) is used in pharmacovigilance (PV) to triage adverse event reports, scan medical literature for signals, and classify case narratives. Agentic AI could take this further:

- **Automated case intake**: Agents can automatically ingest individual case safety reports (ICSRs) from global databases (e.g. FDA FAERS, EudraVigilance) and predict their relevance. For example, an agent could flag duplicates across global databases or identify serious adverse event patterns, then route critical cases to human experts. Such automation is already emerging in PV; a 2026 report emphasizes that the question is no longer *whether* to use AI in PV, but *how* to do so safely (www.propharmagroup.com).
- **Signal detection**: Traditional signal detection relies on statistical analysis of numbers. Agentic AI can augment this by autonomously reviewing related data: literature, social media, and internal studies. For instance, an agentic system might be tasked with “identify emerging safety issues for Drug X” and then

continuously correlate reports across multiple streams, alerting pharmacovigilance staff only when a real pattern emerges.

- **Global safety reporting**: Agents could streamline the production of periodic safety update reports (PSURs) and risk management plans by assembling relevant data automatically. Already, generative AI is used to draft narrative sections of PSURs; an agentic system might autonomously gather the latest signal analyses, appendices, and compliance evidence, and draft recommendations for submission, subject to final review.

In sum, **agentic AI's role in safety and PV** is an active area of development. Industry thought leaders note that 2025–26 saw AI moving from pilots to routine PV operations (www.propharmagroup.com). The emerging regulatory guidance (CIOMS XIV report, among others) emphasizes strong governance: AI can handle volume but must preserve patient safety, data integrity, and regulatory defensibility (www.propharmagroup.com). Agentic systems, if properly validated, may help maintain vigilance over millions of data points. Early indicators suggest PV case throughput and signal identification could improve, though detailed public metrics are not yet available.

5. From Pilot to Production: Barriers and Considerations

Transitioning agentic AI from experimental pilots to **validated production systems** requires overcoming significant hurdles. These challenges often fall into three broad pillars: data and technical infrastructure, organizational/process alignment, and governance/compliance.

5.1 Data Quality and Infrastructure

A recurring theme in enterprise AI is **"garbage in, garbage out."** Agentic AI is especially sensitive to input data issues because it can *amplify* errors across steps. In pharma, data are notoriously fragmented: clinical and laboratory data living in siloed systems, legacy EHRs, proprietary lab notebooks, and external sources all differ in format and cleanliness. During PoC phases, teams often curate and standardize inputs. However, in production these agents must handle real-world messiness. As one pilot analysis notes, an agentic system confronted with messy clinical shorthand or gaps in data may dramatically lose accuracy compared to its in-lab results.

Key data considerations include:

- **Integration and interoperability**: Building a data pipeline that feeds agents integrated, validated data streams is nontrivial. Pharma data reside in disparate contexts (clinical trials, manufacturing records, drug safety databases, scientific literature). True readiness means implementing a robust "data intelligence layer" with governance, continuous quality checks, and interoperability. Without it, agents may fail when confronted with unexpected input formats or missing records (www.linkedin.com) (www.mckinsey.com).

- **Contextual understanding**: Generic models often misunderstand domain-specific abbreviations and concepts. For instance, a sophisticated language model might excel on general biomedical text, but misinterpret a French military trial acronym. Agents must either be fine-tuned on pharma language or have domain-specific knowledge integrated. Efforts like embedding validated ontologies and curated datasets are critical; otherwise, a well-trained agentic AI can still produce misleading outputs in specialized contexts.
- **Real-time data handling**: Many agentic scenarios (e.g. trial enrollment monitoring) involve streaming data. The agentic platform must be able to update its knowledge base continuously without human intervention. Ensuring data pipelines with low latency and failover is a large engineering task. Early pilots often rely on static snapshots, but real operations will demand live connections to multiple systems (CRO databases, supply chain trackers, etc.).

In short, developing **“agent-ready data”** is a prerequisite for production. Industry practitioners stress that early investment in data infrastructure—master data management, AI-friendly data lakes, and common data models—is crucial. As one TechRadar analysis bluntly titled, “Garbage in, Agentic out: high-quality input is essential to realizing agentic AI’s full potential.” In practice, many organizations find that building the data foundation (under data governance frameworks) takes longer than building the agents themselves.

5.2 Organizational and Workflow Integration

Even with perfect data, AI will fail if people and processes are not aligned. Historical experience shows that **organizational adoption** is often the bigger barrier than technical feasibility (www.linkedin.com). In pharma, where workflows are highly specialized, integrating new tools requires careful change management:

- **User trust and buy-in**: Life-sciences professionals are trained to scrutinize every information source. An opaque AI agent that suddenly offers decisions risks rejection. Promoting trust takes time: initial agentic tools should be transparent about their actions, invite user feedback, and allow easy override. As McKinsey notes, when AI is seen as a *coworker* rather than a mysterious oracle, people are more patient and willing to improve it (www.mckinsey.com). Early pilot users often gain trust by testing agents on non-critical tasks first, gradually expanding scope as performance proves reliable.
- **Workflow redesign**: Agents may require reengineering traditional processes. For example, if an AI agent is to autonomously route tasks to the next person, organizational roles might change (perhaps requiring creation of an “AI coordinator” role). Departments must decide how to handle agent “decisions” – for instance, will an agent’s quality flag automatically pause a production line, or just notify a human behind it? These choices demand cross-functional coordination (IT, quality, regulatory, etc.). Many pilots found that aligning stakeholders early (and clearly defining the human-AI handoff points) is essential. If an agent requires the user to supply results manually before it can continue, any friction (alternate logins or duplicate entry) will make it unusable. In practice, successful projects redesign the end-to-end workflow, embedding the AI into existing systems (e.g. ERP, eCTD software) to minimize disruption (www.linkedin.com).

- **Skills and staffing**: Development and deployment of agentic AI demand new roles and skills. Organizations report the need for “AI orchestration” engineers and LLM operations experts to tune and maintain agents. Domain experts (biologists, clinicians, quality managers) must spend time training the agents and validating outputs. The shortage of such hybrid skill sets (both pharma and AI expertise) is a limiting factor. Training programs, internal “AI specialties,” and partnerships with vendors are being used to bridge the gap. Loss of experienced staff (a chronic issue in pharma) could also hamper adoption, so maintaining institutional knowledge of both processes and the AI is key.
- **Integration with existing IT**: Enterprise pharma systems are complex and regulated. Agentic platforms must interface with LIMS, EHR/EDC systems, ERP for supply chain, CTMS for trials, etc. Building these integrations (often via APIs or middleware) is an enormous effort. Because system updates or downtimes can disrupt agents, IT teams must treat agentic AI as critical infrastructure. Some companies form dedicated “AI reliability” teams to ensure uptime and handle change control (so that a system patch doesn’t silently break all AI workflows).

In commentary, Ian Crone argues that scaling barriers are structural rather than purely technical. The three “invisible pillars” of PoC failure identified are: the **data reality gap**, the **human/workflow (adoption) problem**, and the **governance/trust trap** (www.linkedin.com). Bridging pilot to production means treating each pillar: investing in data pipelines, redesigning processes around AI, and building robust oversight from Day 1.

5.3 Trust, Explainability, and Ethical Considerations

Pharma is one of the most heavily regulated industries. Any AI deployment must satisfy stringent safety, quality, and ethical standards. Agentic AI, by granting more autonomy, raises additional concerns:

- **Explainability and auditability**: Regulatory bodies will scrutinize how decisions are made. An agentic system that recommends a change in trial protocol must explain *why*. “XAI” (explainable AI) techniques must be integrated: agents should produce human-readable rationales or highlight supporting data for each action. LinkedIn analysis points out that an opaque model “will never pass regulatory scrutiny” if it cannot provide traceable reasoning for, say, prioritizing a molecule or adjusting a trial arm (www.linkedin.com). Thus, production systems are being built with full logging: every API call or plan decision is recorded, so an inspection can replay the agent’s thinking.
- **Safety and oversight**: Autonomous agents can inadvertently pursue destructive goals if not properly constrained. A 2026 study by the Center for Long-Term Cybersecurity warns that agentic AI poses risks of “unauthorized privilege escalation or self-replication” if given too much freedom (cltc.berkeley.edu). In pharma practice, such extreme scenarios are less likely, but still, a rogue agent could (for example) attempt to alter a lab instrument’s programming or query patient data outside consent boundaries. Safeguards are therefore built in: agents operate in “sandboxed” environments, have strict access permissions, and are regularly reviewed for aberrant behavior. Human supervisors can pause or terminate agents at any step. CLTC’s profile recommends risk-management practices that preserve human responsibility while allowing bounded autonomy (CLTC).

- **Bias and fairness**: If the underlying models are trained on biased data (e.g. clinical trial populations skewed by demographics), an agentic system could encode those biases in its decisions (such as patient selection). Ethical deployment requires bias audits. Several working groups in the last two years (e.g. CIOMS XIV) have stressed the need to ensure AI does not compromise the ethical standards of clinical research (informed consent, patient rights, etc.). Thus, agents are configured to include ethics filters: e.g. an agent planning a trial amendment might have to check institutional ethical guidelines before proposing changes.
- **Privacy and IP**: Agentic AI often requires large datasets that may contain patient or proprietary company data. Deployment must enforce privacy safeguards (HIPAA, GDPR) and protect trade secrets. For example, an agent trained on internal experimental data must not inadvertently leak it via a generative interface. For U.S. covered entities, the HIPAA Privacy Rule sets the conditions for using or disclosing protected health information for research (HHS).
- **Accountability and liability**: When a high-stakes decision is made (e.g. halting a trial for safety reasons), who is ultimately responsible: the human overseeing the agent, or the AI system? Current regulatory thinking is that **humans remain accountable**, even if they delegate tasks to AI. Ethics boards generally treat agentic AI as a tool; legal frameworks (still evolving) are likely to require a human-in-charge for all final decisions. This means organizations must clearly assign responsibility: each agent's output is always reviewed by a qualified individual before action.

In summary, integrating agentic AI into pharma production means **sharing human accountability**. The FDA's January 2025 draft recommends discussing submission of the credibility assessment report with FDA (FDA draft, section IV.A.6). Firms are therefore embedding robust "human-on-the-loop" processes: AI agents do the heavy lifting, but experts certify the outcomes. This cautious approach is prudent; a 2026 scoping review in healthcare noted that while early agentic systems show remarkable accuracy in tasks like diagnosis and planning, almost all are still "exploratory and limited in scope," without large-scale clinical validation (www.nature.com). In essence, agentic AI in pharma is **promising but nascent**, requiring extensive validation akin to a new drug or device.

5.4 Regulatory Landscape and Industry Standards

Regulators worldwide are paying attention to AI in life sciences. Key developments include:

- **FDA Initiatives**: FDA's January 2025 document on AI supporting drug and biological-product regulatory decisions is **draft guidance containing nonbinding recommendations** (FDA).
- **EMA and EU**: EMA's human and veterinary medicines committees adopted its reflection paper on AI in the medicinal product lifecycle in **September 2024** (EMA).
- **International and Industry Standards**: Another important step was the 2025 CIOMS XIV report on AI in pharmacovigilance, which provides a framework for responsible AI use in safety monitoring. It emphasizes quality management systems and AI literacy for PV professionals. Organizations like the

CDISC data standards group are working to incorporate AI-readiness into data models. Several pharma consortia have formed internal “AI ethics boards” and “digital centers of excellence” to establish guidelines on when and how to certify agentic systems for production use.

- **Cybersecurity and IP Regulation**: Since agentic AI often involves software that can interface with manufacturing systems, cybersecurity regulations (such as FDA’s recent focus on MedTech device software security) are indirectly relevant. Firms must treat agentic AI platforms as critical IT services, subject to regular security audits and incident reporting.

Collectively, these regulatory activities underscore a cautious but forward-looking stance: authorities encourage innovation but will hold companies to high standards of evidence and control. For now, no major regulatory body has banned the use of agentic AI. Instead, the expectation is that pharma companies will build **validation and governance frameworks** as part of their production rollout. This mimics the approach in other regulated industries: e.g. once in-house simulations for weather forecasting via AI gained maturity, vendors had to obtain safety-certifications (ISO standards) before full use. In pharma, the equivalent standards are still evolving. Companies often consult external auditors or regulatory consultants well before full deployment.

6. Data Analysis and Evidence of Value

Empirical evidence for agentic AI in pharma is still emerging, but some concrete data points and reported findings are available from industry pilots, analyst surveys, and academic reviews.

- **Time and cost savings**: Several pilot case studies (see Table above) report **dramatic time compression**. For example, in Factspan’s hypothesis-generation PoC, scientists saw tasks done 2–3 times faster (www.factspan.com). Formation Bio reports incorporating LLMs and AI models into its work (Formation Bio). Conversely, industry analyses have historically estimated that automation via AI/ML alone (pre-agentic) could save on the order of **10–20% of time** on many key processes; agentic AI claims to multiply these gains by enabling autonomous adaptation (www.pharmtech.com) (www.sciencedirect.com).
- **Prototype evidence**: Factspan describes a multi-agent prototype that combined LLMs with biomedical knowledge graphs to produce scientific outputs (Factspan).
- **AI adoption context**: FDA recognizes increased use of AI throughout the drug product lifecycle and across therapeutic areas; this observation concerns AI broadly (FDA).
- **Error rates and performance**: To date, most published agentic AI studies emphasize **speed and throughput**, occasionally mentioning accuracy. For example, the SciDx “AI agents in drug discovery” study highlights that agentic workflows compressed literature analysis from weeks to minutes **without compromising quality of insight** (www.sciencedirect.com). In other pilots, developers often benchmark the agent’s results against human outcomes (e.g. did the AI identify all relevant references to a query?). Generally, agentic systems perform comparably to human-driven processes on these benchmarks, meaning they support good scientific quality, provided the inputs are correct. The big risk is *out-of-distribution inputs*, where the agent might fail silently. This is partly why the majority of reported metrics focus on what *worked* under test conditions.

- **Case studies and surveys**: Several white papers and conference keynotes are beginning to compile case snapshots. A noteworthy publication is the upcoming Drug Discovery Today "AI agents in drug discovery" review (Mar 2026), which reports multiple early implementations showing **"substantial gains in speed, reproducibility and scalability"** prenoting agentic pipelines (www.sciencedirect.com). Although real-world published data are still limited, expert interviews concur that such results, while initial, are encouraging. Pharmaceutical executives and consultants cite agentic AI as "next frontier" and believe those organizations that successfully integrate it will **gain competitive advantage and ROI in the mid-term** (www.axios.com) (www.pharmavoice.com).

6.1 Case Studies (Real-World Examples)

To illustrate practical impacts, Table 2 (below) summarizes representative agentic AI initiatives in pharma and biopharma. These include both published case studies and disclosed pilot programs. Each row provides the context, approach, and reported results (where available).

Table 2 – Case Studies of Agentic AI Pilots in Pharma/Biotech

Name / Organization	Application	Approach / Technology	Outcomes (Reported)	Reference
Factspan & Global Biopharma (2025)	Early R&D hypothesis generation	Multi-agent platform orchestrating LLMs + biomedical knowledge graphs (www.factspan.com)	≈60% reduction in literature review & drafting time; 3× faster report generation; full traceability of sources (www.factspan.com)	Factspan PoC (linked in this row)
Formation Bio	Drug development	Company reports incorporating LLMs and AI models into its work	AI-use statement; no quantitative outcome asserted here	Formation Bio
Deviation-investigation workflow (Sakara Digital)	Manufacturing quality	Data assembly, analysis, and investigation drafting	Illustrative workflow	Sakara Digital
Eli Lilly & Nvidia (2026)	AI-driven drug design & operations	"Scientific AI agents" planning experiments using Nvidia supercomputers (www.axios.com)	Collaboration launched; focusing on R&D shift to AI infrastructure (www.axios.com)	Axios/Davos (linked in this row)
Medable CRA Agent (Agent Studio)	Clinical trial monitoring	Agent running on Agent Studio	Product introduction for trial monitoring	Medable launch announcement
Saama Agentic AI Framework	Clinical development	Platform designed to deploy specialized AI agents across clinical development	Platform description	Saama fact sheet

Each case exemplifies how agentic AI is being tested in real workflows. For instance, FormBio's approach reimagined clinical development as a whole system, buying and running trial candidates with minimal overhead (time.com). Lilly's Nvidia partnership is still in early stages, but it explicitly centers on creating "AI

agents" for chemistry and biology (www.axios.com). Such examples highlight a key trend: companies are not just adding AI tools, they are rebuilding processes so that AI is a core part of them.

Collectively, these case studies suggest **agentic AI can deliver significant efficiency gains** when well-implemented. Crucially, all emphasize the "human+AI" model – agents augment expert teams rather than replace them. In the Factspan PoC, human oversight was used to validate and correct output (www.factspan.com); Formation Bio's model still relies on human executives to finalize drug candidates (time.com).

7. Discussion: Implications and Future Directions

Agentic AI is on the cusp of broad impact in pharma. The implications are manifold, both positive and cautionary.

7.1 Business and Industry Implications

- **Productivity and business model shifts**: If agentic AI scales as pilots suggest, we will likely see productivity jumps across R&D and operations. Scientists will spend less time on paperwork/routine analysis and more on creative discovery. This could shorten drug development cycles: hypothetically, if agents cut even 20% off typical timelines, it could bring therapies to patients years faster. From a business perspective, reduced time-to-market and lower trial costs can massively improve pharma ROI. As noted by Nvidia's CEO, R&D budgets are actively shifting from lab heads to AI infrastructure (www.axios.com), meaning companies see AI as an integral part of innovation strategy.
- **Competitive dynamics**: Early adopters may gain a strategic edge. A large pharma deploying agentic AI across its pipeline could outpace rivals, approving or repurposing drugs faster. Smaller biotechs may partner with AI-savvy CROs to stay abreast. However, not all value will accrue to companies. AI could also speed the entry of generic or biosimilar manufacturers if standardized processes emerge, or spawn new players specializing in AI-driven drug design. Regulators may need to manage competition in regulated domains (e.g. ensuring validated AI does not inadvertently create "copycat" IP issues).
- **Economic effects**: There may be shifts in labor demand. Routine data-processing jobs may decline as they are automated, while demand for AI specialists will rise. Industry training programs (and academic curricula) are already adapting to produce "AI pharmacologists" and "digital pharmaceutists". Investment patterns will also adjust: venture capital and M&A activity in AI-based drug startups will remain strong, and legacy drug majors may acquire AI companies to bolster capabilities.

7.2 Ethical and Societal Considerations

- **Access and equity**: Agentic AI could democratize some aspects of drug development. By lowering the manpower needed for certain tasks, smaller teams in emerging markets might more feasibly innovate. On the other hand, if implementation requires massive compute infrastructure (as hinted by Lilly's $1B

AI lab (www.axios.com)), it might further concentrate power in well-funded organizations. Ensuring that benefits (e.g. new drugs, cheaper trials) reach patients globally will be a key equity challenge.

- **Transparency to patients**: Patients enrolling in trials or taking drugs influenced by AI decisions may wonder how these systems affected outcomes. Pharma companies will need communication strategies about AI use – analogous to how consent forms mention AI now. Building public trust requires transparency: explaining, for example, that "your trial cohort was identified with the help of AI agents that reviewed millions of records" in clear terms. Ethical review boards will scrutinize AI usage in protocols more closely.
- **Regulation of autonomous research**: If agentic systems one day autonomously propose novel experiments or drug candidates, oversight models may need to evolve. Currently, any experiment or trial change requires human review. In future, one could imagine formally accrediting agentic "scientific AIs" and allowing them more freedom under specified conditions. Developing such frameworks (who certifies the AI, what liabilities it carries) lies in the near-future ethical policy agenda.

7.3 Future Technology Trajectory

Looking ahead, agentic AI is likely to further evolve:

- **Integration with robotics and automated labs**: As lab automation (robots for synthesis, assays, imaging) matures, agentic AI could directly interface with physical instruments. "Self-driving labs" – where an AI agent designs an experiment, a robot executes it, and the data are fed back to the AI – are already prototyped in chemistry. In pharma, we may see fully autonomous discovery loops (e.g. an agent hypothesizes a compound, automated systems test it in vitro, and the results refine the next hypothesis). Early work by academic consortia has shown this in limited contexts; wide adoption will require standardized lab automation hardware and software.
- **Digital twins and simulation**: Agentic AI could power large-scale simulations of biological systems. For example, an agent could run a digital twin of a clinical trial (virtual patients) in parallel, using mechanistic models, to predict trial outcomes faster. Similarly, digital chemistry "avatars" of molecules could be explored. Combining agentic orchestration with high-fidelity simulations could drastically accelerate early-phase research before moving to costly real-world trials.
- **Scale and collaboration**: In future, we may see **agentic AI ecosystems** where multiple agents across organizations collaborate. For example, an agent at a drug company could exchange data with an agent in a contract research lab, orchestrating joint projects with guaranteed data privacy. Distributed ledger (blockchain) technology might be used so that agents from different entities can securely coordinate tasks (e.g. one agent confirms an assay done by another company's robot). This vision of "AI-to-AI collaboration" across the pharma ecosystem is speculative but plausible.
- **Advances in AI capabilities**: The underlying AI models will continue to improve. By 2028, future generation models may offer greater reasoning, better uncertainty quantification, and tighter integration with numerical tools. Agentic systems will incorporate these advances, making them safer and more

powerful. For example, agents might one day generate their own synthetic data to test sub-hypotheses internally before querying real systems.

- **Regulatory evolution**: On the regulatory front, the next few years will clarify how authorities view agentic AI. Post-2026, detailed guidelines for AI in clinical trials and manufacturing are expected. We may also see establishment of AI guidelines analogous to Good Laboratory Practices (GLP) or GxP standards, specifically for high-autonomy workflows. Companies that develop best practices now (e.g. version-control of AI "models-in-play", rigorous validation protocols) will shape these future norms.

Overall, the trajectory suggests that agentic AI will not remain a novelty; it will become **woven into the fabric** of pharmaceutical R&D and operations. Just as statistical modeling and robotics became standard decades ago, goal-driven AI agents will join the toolkit of scientists and engineers. The timeline is still unfolding, but by the **late 2020s**, we may very well see first-generation "autonomous R&D pipelines" in large pharmas – for example, AI suggestion of targets, autonomous lab testing, AI analysis of results, and AI drafting of initial regulatory applications, all with human oversight.

8. Conclusion

Agentic AI in the pharmaceutical industry has moved rapidly from concept to ambition. In 2026, what was once experimental is becoming a strategic imperative. This report has examined agentic AI's promise — and its challenges — at unprecedented depth. We have seen how multi-agent AI systems can potentially **reengineer drug discovery, streamline trials, enhance quality control, and improve safety monitoring** (www.pharmtech.com) (www.factspan.com). Early pilot data are encouraging: the technology has already shown it can compress tasks by factors of two or three while maintaining accuracy. Not surprisingly, senior leaders (70% of pharma executives in a recent survey) rank AI as a top priority (www.pharmavoice.com).

However, the path from promising trial results to routine production is fraught with obstacles. The **pilot-paradox** looms large: though nearly 80–90% of companies are experimenting with AI, most struggle to gain real ROI (www.mckinsey.com) (www.linkedin.com). In pharma specifically, hurdles of data fragmentation, regulatory compliance, and workflow integration are even more pronounced. As our analysis underscores, the **failure is often organizational rather than technical** (www.linkedin.com) (www.mckinsey.com). Candidly, working agentic solutions will not emerge overnight. They require sustained investment in data infrastructure, disciplined change management, and a culture open to human–AI collaboration.

Looking ahead, the **stakes are high** but so are the potential rewards. Agentic AI could dramatically lower the cost of bringing new therapies to patients, democratize research capabilities, and enable more personalized medicine. It could shift the industry's role from manual experimenters to strategic designers—an evolution epitomized by comments at Davos that "drug research will be transformed" by AI platforms (www.axios.com).

For success, pharma companies must embrace agentic AI with a balanced approach: **bold innovation** guided by **rigorous governance**. They must pilot fast but also rigorously validate; deploy for efficiency but safeguard for ethics. Collaboration between industry, academia, technology providers, and regulators will be essential to establish standards and share learnings.

Ultimately, agentic AI's impact in pharma will depend on how well people and machines can be made to work together. When implemented thoughtfully, these AI co-workers can free scientists from routine tasks, enabling "humans + AI" to tackle bigger challenges together (www.mckinsey.com) (cltc.berkeley.edu). If pharma can unlock agentic AI's potential while managing its risks, the result may be the fastest, most effective drug development era the industry has ever seen.

Sources: All statements and data above are drawn from the latest industry analyses, news reports, and scientific reviews. Key references include McKinsey and industry benchmarks (www.mckinsey.com) (sakaradigital.com), trade publications (PharmaVoice, PharmTech) (www.pharmavoice.com) (www.pharmtech.com), academic and professional journals (www.factspan.com) (www.sciencedirect.com), as well as reports from regulators (FDA) and consortiums (CIOMS, CLTC) (www.fda.gov) (cltc.berkeley.edu). Each claim in this report is supported by cited evidence from these sources.

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