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IMPLEMENTATION OF AI IN U.S. CORPORATIONS IN THE PHARMACEUTICAL INDUSTRY

Thesis submitted in fulfillment of the requirements for the degree of

Bachelor in Economics and Business

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Academic Year: 2024/2025
Date of Submission: June 2025

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10.1 References

1. Introduction

1.1 Defining AI in Pharmaceutical Operations

Artificial Intelligence (AI) is rapidly reshaping the face of the pharmaceutical industry. In its broadest definition, AI describes computational systems which learn from experience, identify patterns, and make decisions with little or no human intervention. Within the field of pharmaceutical operations, AI takes multiple forms: machine learning drug discovery algorithms, natural language processing software programs for regulatory reporting, computer vision systems for checking quality during manufacturing, and intelligent chatbots or virtual assistants for patient interactions. AI contributes to the entire pharmaceutical value chain. In R&D, predictive models can simulate compound interactions, assess molecular characteristics, and optimize screening pipelines. In clinical trials, AI maximizes patient recruitment by mining electronic health records and facilitates adaptive trial designs that learn in real time. Manufacturing increasingly relies on AI for predictive maintenance and batch consistency, and in post-market phases, pharmacovigilance is enhanced using real-world data analytics and algorithmic safety monitoring.

Moreover, AI has begun to impact further upstream steps of molecular target discovery through the integration of genomics and bioinformatics. Companies are beginning to rely more heavily on AI-enabled platforms to screen large biological datasets, identify new disease mechanisms, and suggest potential compound candidates. In production, AI technologies make supply chain resilience through means of demand forecasting, automated quality inspection, and adaptive process control—abilities that became of particularly significant importance when COVID-19 struck.

Patient-level innovation is also on the scene. AI technologies are being integrated into digital medicine platforms to monitor adherence, predict relapse, and customize up treatment schedules. This may take the form of wearable sensors, AI-driven mobile apps, and support robot assistants, all components of an expanded definition of medication engagement beyond the pill.

1.2 Research Question and Objectives

The thesis is set to respond to this research question not only by outlining AI applications but by describing them in their strategic, organizational, and regulatory settings. Thus, the project attempts to look beyond mere cataloguing of use cases. It tries to understand the implications of AI integration for pharmaceutical firms' modes of operation, competing, and evolving under the challenge of a tightly regulated market. Along the way, the research offers valuable input to corporate readiness, governance, and innovation initiatives driven by digital transformation.

This thesis responds to the following question: How and to what extent are U.S. pharmaceutical firms embracing artificial intelligence, and what strategic projects are they undertaking?

In response to this question, the research aims to:

- Map where and how AI is being utilized in pharmaceutical operations

- Identify organization strategies for embracing AI, including internal build and partnerships
- Examine the function of regulation, compliance behavior, and public disclosure in AI adoption
- Connect empirical trends to established theories of innovation management and organizational behavior

1.3 Significance of the Research

What sets the pharmaceutical industry apart from other technologically accepting industries is its precise blend of scientific nuance, public health duty, and rigid regulation. AI uptake in this industry therefore must overcome a higher threshold of proof. The margin for error is low, and stakeholder expectations—ranging from regulators to investors to patients—are high.

This positions the pharmaceutical industry as a suitable case study of responsible AI scaling. In addition, U.S. companies are burdened with global competitiveness. China and the European Union have launched national AI strategies with laser-like intensity on healthcare innovation. To be able to sustain leadership, American pharma firms will have to navigate both digital transformation and geopolitical alignment.

Finally, understanding about AI use in pharma has public interest implications. With precision medicine and data-driven healthcare on the rise, AI will increasingly influence what treatments are made available, to whom, and how health outcomes are monitored. These ethical and practical dimensions underscore the relevance of the research question.

The pharma industry is subject to a unique mix of innovation stress and regulation. Medicine development is a labor-intensive, capital-hungry, and clinically and legally risky process. AI offers the potential to reduce uncertainty, compress time-to-market, and enhance clinical decision-making. Nevertheless, its use is complicated by the need for validation, transparency, and data privacy—especially within the U.S. market, where Food and Drug Administration (FDA) and Health Insurance Portability and Accountability Act (HIPAA) regulations create high levels of compliance.

It is useful to understand how drug companies are able to sustain technological aspiration and regulatory control. The conclusion of this thesis has relevance not only for practitioners in the industry but also for regulators, investors, and researchers interested in seeing where new technologies meet organizational adaptation.

1.4 Methodological Approach and Chapter Overview

Methodologically, the thesis employs a qualitative comparative approach supplemented by data triangulation in the guise of corporate reports, regulatory filings, and academic literature. The standard for AI adoption was strict: public, document-backed implementation was the only standard. Adherence to public, document-backed implementation ensures analytic rigor at the exclusion of risk of speculative inference on the basis of press coverage or non-peer-reviewed claims.

The organization of the thesis is structured on the principle of progressive deepening of analysis. From industry-level book and trend in strategy (Chapters 2 and 3), the debate trickles down to firm-level action and strategic articulation (Chapters 4 and 5). It then deals with cross-sectional integration and theory analysis (Chapters 6–8), before wrapping up with practical advice and academic implications (Chapters 9–10). APA referencing has been employed throughout, with appendices providing supportive data such as the full firm list, graphical representations, and document excerpts.

The thesis is preceded by a literature review in Chapter 2, which places AI in the context of pharmaceutical innovation and identifies gaps in previous academic research. Chapter 3 provides an explanation of the methodology, including a screening of 400 drug firms using a Stata dataset. Of these, 11 firms were shortlisted for detailed analysis based on documented implementation of AI through regulatory documents and company reports.

Chapters 4 and 5 present evidence on AI adoption and firm-level strategies. Chapter 6 examines strategic patterns like internal development vs. external development and AI framing in public disclosures. Chapter 7 addresses implications of regulation and data privacy. Chapter 8 synthesizes cross-cutting themes and links them to innovation theory. Chapter 9 summarises the findings and offers suggestions for future research. Chapter 10 possesses full references and related appendices, including source documents and visual materials.

2. Literature Review

2.1 Academic Research on AI in the U.S. Pharmaceutical Industry

The academic literature on artificial intelligence (AI) within the pharmaceutical industry has expanded dramatically in recent years, as increasingly traditionally research-driven industries rush to implement computational technologies. AI is no longer viewed as a recently invented add-on technology, but as a fundamental operational and strategic capability that supports innovation and productivity. Specifically, the U.S. pharma industry, characterized by high R&D intensity, data-intensive environments, and regulation, has commanded more and more attention from researchers and analysts interested in knowing how AI is revolutionizing both clinical and commercial operations.

The vast majority of research centers on AI in drug discovery. Conventional processes based on drug discovery have vast reliance on trial-and-error techniques, manual compound screening, and prolonged laboratory testing. On the other hand, existing research describes how predictive modeling and deep learning now make it possible for scientists to simulate molecular behavior, identify target compounds, and reduce discovery time. For instance, Mak and Pichika (2019) demonstrate how the application of algorithmic models can predict absorption, toxicity, and protein-binding ability of candidate drugs before clinical trials, thereby improving accuracy and saving money.

Beam and Kohane (2018), writing about biomedical informatics, also show that machine learning approaches enable researchers to associate molecular signatures with phenotypes of disease with some degree of accuracy that is not possible in conventional lab conditions.
Another widely studied application is the optimization of clinical trials. Expenses and intricacies of clinical investigation are well documented, particularly in the United States where regulatory and logistical challenges have a tendency to slow patient enrollment and analysis of data. Academic papers by Sloan and MIT authors (e.g., Brynjolfsson and McAfee, 2017) highlight how AI supports adaptive trial design through better patient matching with protocols using data from electronic health records (EHRs) and real-world evidence (RWE) data sets.

AI solutions help with monitoring patient safety, detecting adverse events earlier, and verifying trial outcomes under different circumstances. These skills not only improve speed and accuracy but also improve compliance with FDA reporting regulations.
Less frequently, but more powerfully, researchers are turning to AI in pharma manufacturing and logistics. Articles published in applied sciences and pharmaceutical operations journals examine the use of AIto monitor supply chains, anticipate inventory requirements, and perform predictive maintenance on manufacturing lines (Kumar et al., 2020). While such applications lack the sex appeal of drug discovery, they play a crucial role in scaling innovation, especially when supply chains are under stress globally. Post-marketing surveillance is also being viewed by Topol (2019) as a growing AI use, with machine learning algorithms being used to detect trends in patient-reported outcomes and track efficacy in larger, non-controlled groups.

There is also fresh work on the way in which the pharma sector is building AI capabilities within their organisations. There is some writing on internal data science units and AI research laboratories, and some writing on co-development partnerships with tech firms and universities. What all these frameworks share is the growing recognition that AI must be embedded not just technically, but culturally and strategically within pharma conglomerates.

In total, the literature provides strong evidence that AI is utilized across the pharma value chain, but also reports some blind spots. Most articles focus on technical potential, while fewer focus on strategic framing, disclosure practices, or long-term implementation outcomes. In addition, there is less comparative research across firms or geographies—particularly in the U.S., where regulatory pressure and investor expectations create added challenges and incentives to AI use.

2.2 Digital Transformation and Strategic Integration of AI in Pharmaceutical Firms

Digital transformation in the pharmaceutical industry goes well beyond mere automation or data transfer. Over the last ten years, it has evolved as a multi-faceted, inter-disciplinary process devoted to the incorporation of digital technologies—like artificial intelligence—into core business and scientific procedures. Scholars have researched digital transformation in healthcare from many angles, but in recent literature, there is a focus on learning how such efforts change entire enterprises' corporate cultures, not single functions. For U.S.-based

pharma companies, this is particularly germane. These organizations operate in a high-speed competitive and highly regulated market demanding innovation, quickness, and conformance—basically the strengths of AI when deployed strategically.

Digital transformation reports in pharma highlight that AI can only succeed if it's integrated not as a tool but as a capability. Hess et al. (2016) characterize digital transformation as a multi-faceted phenomenon that includes IT infrastructure, culture of data, and decentralized models of innovation. In pharmaceutical firms, this translates into structural changes like establishing specialized AI governance boards, opening up to internal innovation centers, and creating cross-functional AI teams with data scientists, medical researchers, and compliance officers. Compared to ad-hoc digital innovations, such change is deeply strategic and typically supported at the executive level.

Digital maturity is increasingly being linked in empirical research to organisational flexibility and sustainable innovation outcomes. Consistent with a longitudinal study by Westerman et al. (2014), companies that invest in digital competence alongside leadership development beat the competition in time-to-market, clinical success rates, and market share. Inside the pharma space, that would mean faster compound screening, more efficient clinical protocols, and improved regulatory filings, as seen through the strategy of players like Pfizer and Takeda.

Those firms are what in literature has been described as "transformational use of AI," where digital solutions are not pursued as isolated endeavors but become part of the company's innovation process.

Not every digital strategy is the same, though. While others go for end-to-end digitalization, others try to digitalize particular functions like R&D or logistics. Academic studies conducted by Bharadwaj et al. (2013) suggest that these differences are not only resource-driven but also the firm's risk-taking, regulatory approach, and technological ambitions. Within pharma firms, where the cost of failure is high, AI is typically taken up cautiously—ideally in partnership with academic facilities or tech firms—to offer scientific and regulatory credibility. Such co-development helps fill internal competence gaps while ensuring outputs from AI align with FDA or EMA regulatory requirements.

In the USA, with drug companies expected to innovate and adhere to stringent compliance, digital transformation takes on a new role. Value-driven healthcare being on the rise, patient-centric models, and real-world evidence all contribute to increasing reliance on AI for continuous examination of data and tracking of outcomes. Writers like McKinsey's Chui et al. (2020) argue that the most successful pharma companies are those which treat AI as a horizontal capability and not as a department,similar to regulatory affairs or quality assurance. This is supported in analyses of the industry ranking companies by their digital health scores and readiness to integrate data.

As a whole, the literature recognizes that AI is no longer its own independent effort separate from digital transformation—it is its key facilitator. U.S. pharmaceutical companies lead the charge in this revolution, but their accomplishment rides on linking AI initiatives with broader strategic goals, risk management frameworks, and models of long-term innovation. The subsequent section will expose where the literature is incomplete and how this thesis completes those gaps via empirical evidence.

2.3 Research Gaps and Reason for This Study

Even though the literature available shows very good coverage of how AI is transforming drug discovery, clinical trials, and pharmaceutical supply chain logistics, there are crucial gaps which must be investigated. Much of the scholarly focus to date remains function-based, often addressing either the technology or particular operational benefits associated with AI. What is not well explored is how firms make use of AI across their enterprises, particularly in terms of strategic and disclosure uses, and how firm-level strategies differ within a shared regulation and market environment such as the U.S. pharma sector.

Some research mentions enterprise-level AI take-up, but these are often not comparative in design. As an example, they will say standalone use cases in patient care or R&D, but fail to link these with digital infrastructure, governance, or competitive strategy. More importantly, they do not frequently ask how companies disclose their AI projects in public filings and whether the disclosures are proportional to the extent of implementation. This is particularly relevant where regulatory interest and investor pushback intersect—such is the case with pharmaceuticals.

Additionally, academic studies of AI are based on unweighted or outdated case studies. Some are cases of multinational companies but with no regulation or market control for U.S.-based factors. Some are very survey-dependent measurements without verification against firm disclosures, and so there's a perception-day-to-day business gap. The result is a disconnected picture that does not take into account how firms build internal AI environments, fund their projects, or work with external technology partners.

This thesis seeks to get around these limitations by embracing a document-supported, company-level method of tracing AI uptake. The research includes 11 pharma companies with publicly confirmed AI adoption in core functions. Each example is assessed not only in terms of where AI is applied, but also in terms of how it is presented, covered, and placed within broader organisational agendas. The study employs annual reports, investor letters, and SEC filings to base the analysis on verifiable facts, aligning it with both scholarly expectations and actual practice.

In doing so, this study aims to make a contribution to the still-exponential but incomplete corpus of literature on digital transformation in pharma, offering insight into the trends, contrasts, and direction of AI adoption by U.S.-headquartered pharmaceutical firms. It also provides a baseline for future research into comparative sectoral take-up, regulatory effects on digital conduct, and disclosure strategy in technology deployment.

3. Methodology

3.1 Data Collection and Selection Criteria

The methodology employed in this thesis begins with identifying a sample of pharmaceutical companies with confirmed operations in the United States. Data collection focused exclusively on firms with publicly disclosed AI initiatives between 2019 and 2024. The selection was guided by clear inclusion criteria: a company was only considered if it explicitly referenced AI implementation in formal corporate communications such as annual reports, 10-K or 20-F SEC filings, investor briefings, or verifiable press releases. This document-based approach, rather than relying on

interviews or third-party databases, allowed for the systematic validation of AI integration through credible, corporate-authorized narratives.

A preliminary dataset containing over 700 pharmaceutical companies was filtered down to 11 firms meeting the disclosure threshold. This filtration ensured that the analysis was based not on speculative forecasts or general digital transformation rhetoric, but on specific, documented cases of AI integration. By limiting the sample in this way, the study avoids issues of uneven disclosure and provides a higher confidence in the comparative insights drawn from the dataset. This approach aligns with the methodological framework described by Yin (2014) for multiple-case study designs that require rigorous source triangulation.

In selecting these firms, special attention was paid to avoid duplication and inconsistencies in reporting. Sources such as investor relations portals, public SEC databases, and corporate digital health portals were used to extract primary data, ensuring that each instance of AI use could be supported by at least one formal citation. This strategy helps ground the thesis in transparency and replicability, two core principles of qualitative corporate research.

3.2 Verifying AI Adoption

To verify AI implementation, each company's public disclosures were examined in depth using keyword-based content analysis. Terms such as 'artificial intelligence,' 'machine learning,' 'data science,' and 'automation' were flagged in annual reports and filings. Mentions were only included in the analysis if they referred to practical, operational usage of AI—such as applications in R&D, clinical trials, supply chain, or regulatory affairs—rather than speculative intent or future planning. This follows the methodological recommendations by Saunders et al. (2019), who emphasize content validation as a key step in empirical research that draws from publicly available corporate literature.

Where ambiguity existed—for instance, in firms that referenced AI-related partnerships without clarifying their functional scope—additional sources were reviewed to triangulate the intent and depth of the AI application. These sources included technology vendor reports, industry whitepapers, and news coverage directly linked to the pharmaceutical firm's initiatives. If AI references could not be corroborated by formal documentation, the firm was excluded from the final sample. This rigorous verification process ensures that every case considered in this thesis meets a uniform threshold of disclosure credibility.

3.3 Scope of Analysis and Functional Categorisation

The scope of the analysis was limited to operational and strategic implementations of AI in core pharmaceutical functions. These included drug discovery, preclinical research, clinical trials, regulatory documentation, manufacturing and logistics, and post-marketing surveillance. Each company's application of AI was categorised under these functions, and cross-referenced with disclosure type, adoption depth, and frequency of mention. This functional mapping is consistent with the thematic content analysis methods proposed by Braun and Clarke (2006), who advocate for grouping qualitative content around practical relevance rather than abstract categorization.

By organizing use cases functionally, the study was able to identify commonalities and divergences across firms, not just in terms of what technologies were deployed, but also where and how deeply they were embedded into business models. This framework also facilitates the graphical representation of the findings, as presented in Chapter 5. It ensures that discussion is not just

descriptive but also comparative, lending greater analytical weight to observations about sectoral maturity, strategic readiness, and organizational ambition.

3.4 Analytical Framework

The study uses a qualitative comparative methodology to evaluate patterns in AI implementation across firms. This analytical choice allows for contextual interpretation of how pharmaceutical companies frame and execute their AI strategies. The framework draws from Miles and Huberman's (1994) approach to cross-case analysis, which involves coding data for key themes—such as strategic positioning, operational depth, and reporting language—and mapping these against organizational variables like company size, global presence, and level of internal AI capability.

Special emphasis was placed on the tone and frequency of AI references within public disclosures. Firms that emphasized AI in visionary or enterprise-wide terms were differentiated from those with more tactical or niche references. These distinctions were then compared with actual use cases and organizational investments, such as internal AI labs, strategic partnerships with technology firms, or cross-functional innovation teams. The outcome is a rich dataset that balances what companies say about AI with what they actually do, contributing to a nuanced understanding of strategic integration.

All findings were recorded in a qualitative matrix, aligning each firm's AI profile with its corporate strategy and operational footprint. This matrix is presented visually in Chapter 5, and serves as the empirical backbone of the thesis.

4. AI in the Pharmaceutical Industry

4.1 AI Applications Across Pharmaceutical Functions

Artificial intelligence has transformed how pharmaceutical companies operate, injecting velocity, precision, and adaptability into sluggish and costly procedures in the past. In the US pharma sector, AI application spans several arenas, yet R&D has been the best established and acknowledged field of adoption. AI is extensively used to enable early-stage drug discovery, particularly by molecular modelling and predictive analysis. Algorithms can screen thousands of compounds to identify ones apt to bind well with a target, reducing lab testing to an extreme degree (Mak & Pichika, 2019).

Following the discovery phase, clinical trials are the second key area for AI implementation. Traditional clinical trials are plagued with well-documented inefficiencies like patient recruitment sluggishness, inconsistent data collection, and expensive late-stage failure rates. AI is utilized to find eligible participants via inspection of real-world evidence, i.e., medical histories and genomic libraries, making recruitment quicker and more efficient (Brynjolfsson & McAfee, 2017). In addition, machine learning algorithms today assist in monitoring trial progress, predicting adverse events, and real-time modification of trial protocols.

In manufacturing and logistics, AI technologies support the continuity of quality production, inventory control improvement, and waste reduction. Predictive maintenance software monitors equipment performance and forecasts future faults before they cause costly downtime. Several US

businesses have incorporated AI tools into their supply chain systems, particularly since the COVID-19 pandemic revealed vulnerabilities in international pharmaceutical logistics (Kumar et al., 2020).

Regulatory space is also starting to benefit from AI. Certain companies, such as Takeda, have begun employing generative AI models to mechanize the writing and formatting of the regulatory filings so that they are compliant and require less manual input time. In a very regulated setting like the U.S., where FDA regulation is extensive and diligent, these technologies provide a major boost in terms of efficiency and accuracy.

AI is also being utilized in pharmacovigilance—tracking drugs after they have been released into the market. Using algorithms that are trained using data from social media, mobile health apps, and electronic health records, pharmaceutical firms can detect adverse events faster and respond to patient criticism more quickly. This improves patient safety and helps the firms remain regulatory compliant while boosting public trust (Topol, 2019).

In total, AI in the pharmaceutical industry has moved beyond isolated pilot projects. It now permeates critical business processes along the value chain. U.S. pharmaceutical firms have increasingly adopted these technologies, driven by the dual imperatives of scientific advancement and operational efficiency. As will become evident in the following sections, the extent of AI adoption and the approach to doing so vary considerably by company, depending on company structure, resources, and strategic priorities.

4.2 Industry Environment and Trends of Innovation

The uptake of artificial intelligence (AI) by the U.S. pharmaceutical industry has been matched by profound transformation of the broader industrial environment. Pharmaceutical firms are now more and more asked to deliver faster innovation, increased openness, and operating efficiency as global healthcare systems grow more advanced and competitive. This macroeconomic and regulatory landscape has driven adoption of digital technologies, with AI at the core of innovation and not as an add-on technology.

One of the foremost environmental drivers of AI adoption is increasing pharmaceutical development cost. DiMasi et al. (2016) put the cost of developing a new drug compound at over $2.6 billion, and development periods typically take 10 to 15 years. Pharmaceutical firms are turning more and more to AI in order to accelerate early-stage development and improve trial design. Industry reports (McKinsey & Company, 2022) outline how businesses employing AI models for screening compounds, simulating biological interactions, or maximizing trial recruitment have significantly condensed R&D timelines and improved attrition rates.

Concurrently, a regulatory shift is taking place in the United States that increasingly promotes digital innovation. Regulatory agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) are exploring adaptive trial design, patient-reported outcome measures, and digital biomarkers. These models enable companies to file real-world evidence (RWE) and digital health data as part of their regulatory submissions. Therefore, companies that invest in AI technology with capabilities to mine real-world data sets or document automated

compliance have a higher likelihood of being able to keep pace with these evolving standards (FDA, 2023).

Another significant factor is the location of the U.S. pharmaceutical industry close to the global tech world. The majority of pharma companies, especially those with headquarters near technology hubs like Boston and San Francisco, have established strategic partnerships with AI firms. Collaborations such as Sanofi's work with Exscientia or Novartis's alliance with Microsoft exemplify how pharma is drawing directly from Silicon Valley's innovation ethos. These relationships accelerate capability development and create hybrid teams skilled in both clinical science and computational design (PricewaterhouseCoopers, 2021).

Additionally, the investor landscape has shifted to accommodate digital transformation. Public and private investors alike now factor pharmaceutical companies not only on pipeline value but also on technology readiness. As a result, AI deployment is increasingly mentioned in quarterly earnings calls, annual reports, and ESG disclosures. Organizations that outline clear AI strategies are perceived as visionary and robust, particularly during economic uncertainty (Accenture, 2021).

From the workforce perspective, the transition to AI and automation is also reshaping the labor force. US pharmaceutical firms are expanding their hiring to outside the usual biomedical qualifications to incorporate data scientists, algorithm specialists, and systems engineers. The transition is an indicator of a broader redefinition of pharma innovation as being something that requires the coming together of multiple fields. Internal development initiatives, cross-skilling, and industry-academia fellowships are becoming more common as firms invest in future-proofing their pool of human capital (Bersin, 2022).

Strategic and cultural transformations of the companies themselves are also implicated. Hess et al. (2016) and Westerman et al. (2014) studies have indicated that digital transformation is not just about investment in tools but leadership and mindset too. Companies need to incorporate AI into strategic planning cycles, executive dashboards, and KPIs. This is particularly the case in the large U.S. pharma firms where integrating R&D, regulatory, and commercial activities is necessary to realize the full potential of AI.

Lastly, competitive benchmarking once again mandates the adoption of AI. Industry organizations, innovation rankings, and benchmarking reports score pharmaceutical firms on digital health and AI maturity on a regular basis. Falling behind the competition in terms of these rankings can not only harm brand reputation but also partnership and licensing deals. As more firms drive AI deeply into organizational operations, others are put under pressure to do the same in order to keep pace or fall behind competitively (IQVIA, 2022).

Finally, U.S. pharmaceutical company adoption of AI is not being done in isolation. Instead, it is the culmination of overlapping and interdependent forces—rising R&D costs, regulatory transformation, talent shortages, shareholder pressures, and competitive benchmarking. Together, these drivers create an environment that makes AI attractive and unavoidable for firms eager to preserve innovation and operational excellence in the coming decades.

4.3 Relevance of AI Adoption to U.S. Pharmaceutical Corporations

Adoption of artificial intelligence (AI) is of particular relevance to U.S.-based pharmaceutical enterprises due to their distinctive institutional, financial, and technological context. Contrary to emerging market or state-directed health economy businesses, U.S. pharma businesses possess a private, for-profit structure with extensive market exposure, investor scrutiny, and regulation regimes. These conditions raise incentives as well as challenges that determine the introduction and expansion of AI.

One of the salient aspects of the U.S. pharma industry is that it is close to the world-leading digital infrastructure. Silicon Valley, the Boston innovation corridor, and a few research centers for AI are present in the United States. This proximity in location and in thoughts provides pharmaceutical firms with access to cutting-edge computational facilities, recruitment of AI experts, and collaboration with data science thought leaders. In turn, companies such as Pfizer and Amgen have been able to invest in proprietary AI platforms for predictive analysis and drug screening and place themselves competitively in the international pharmaceutical market (Pfizer, 2022).

Besides technology readiness, U.S. firms also benefit from access to capital. They are predominantly listed on major stock exchanges and hence enjoy access to enormous amounts of investment capital. Institutional investors now need most proof of digital maturity and innovation pipelines. Those firms best able to demonstrate AI-driven efficiencies or breakthroughs are rewarded with valuation premiums, increased analyst confidence, and more shareholder interest. Such a financial ecosystem acts as a catalyst for rapid AI experimentation, especially in high-risk, high-reward categories like oncology or neuroscience (Goldman Sachs, 2023).

Furthermore, the U.S. regulatory environment is turning more friendly to AI innovations. The FDA has introduced various digital health frameworks like software-as-a-medical-device (SaMD) and adaptive trial pilot programs. These portals offer pharmaceutical companies with a roadmap for integrating AI into regulatory filings, thereby reducing uncertainty and ensuring easier uptake. The use of AI in automating regulatory paperwork by Takeda is just one example of how U.S.-based drug companies are capitalizing on this opportunity (Takeda, 2023).

Organizational experimentation is accepted culturally by U.S. pharma companies. Many have established dedicated AI or digital health departments, hired chief digital officers, or created cross-functional steering committees to guide data strategy. This ingraining of AI expertise at the structural level reflects more pervasive shifts toward agile models of governance that emphasize responsiveness, risk management, and innovation. Eli Lilly's application of digital biomarkers in its clinical processes demonstrates how businesses are innovating outside conventional drug development (Eli Lilly, 2022).

There is also a trend towards scaling public-private partnerships. U.S. companies often collaborate with government research centers, non-profit health data repositories, and university laboratories to co-develop AI algorithms for rare conditions or underpenetrated groups. Not only does this enhance public confidence but also provides companies with unique datasets and validation strategies that would be hard to replicate on their own (NIH, 2022).

Finally, the level of competition in the American market guarantees ongoing innovation. There are so many firms vying to own therapy and most blockbusters facing patent cliffs that AI offers a method of

speeding up cycles of discovery, reducing trials, and extending product life. Those who lag behind AI risk not only to lose out on these efficiencies but also lose out on turf in licensing, collaboration, and takeover. As industry commentators have noted, digital laggards are less attractive to partners and investors (Deloitte, 2021).

In a nutshell, AI is not only relevant to American pharma companies—but it is fundamental to their competitive positioning. The concurrence of technological access, financial capability, regulation adaptability, organisational readiness, and competitive need makes the United States an environment facilitating pharma AI integration. As this chapter illustrated, the forces surrounding AI uptake must be understood within this multi-dimensional framework to grasp its overall effectiveness on corporate innovation and health outcomes.

5.1 Certified AI Adopters

Here, an overview of U.S.-affiliated pharmaceutical companies certified to have embraced artificial intelligence (AI) as of 2024 is provided. Identification and certification of AI adoption are drawn from official records, including investor reports, 10-K and 20-F filings, press releases, and company statements. Eleven pharmaceutical companies have been certified as existing adopters of AI, exhibiting different depth of integration and strategic priority.

Adoption of AI is common in fields such as drug discovery and clinical trial design but vastly varied in scope and intensity. Some companies such as Pfizer and Novartis have adopted enterprise-scale AI strategies across R&D, clinical, and regulatory functions. Others, such as Takeda or Boehringer Ingelheim, focus on functional use cases such as regulatory automation or oncology research. In the majority of cases, adoption is promoted through strategic cooperation with technology firms, research institutions, or AI-focused biotech companies, which all represent collaborative capability-building efforts.

Pfizer is a classic example of extensive AI adoption. It has used supercomputing and predictive modeling to accelerate R&D, most recently in the development of Paxlovid. According to its 2022 annual report, Pfizer's use of AI is crucial for both pipeline expansion and regulatory issues, making the company a digital trailblazer in its industry (Pfizer, 2022).

Similarly, Amgen has also used AI for its biologics pipeline. In its partnership with Generate Biomedicines, Amgen employs AI to model protein interactions and develop new therapies. In its investor disclosures, it demonstrates how AI supports candidate selection and cycles reduction (Amgen, 2022).

The strategy of Eli Lilly for integration includes working with Genetic Leap to develop machine learning-based RNA drugs (Eli Lilly, 2022). They use their AI technologies to assess trial candidates, provide safety monitoring, and enhance clinical decision-making.

Roche, which is a privately held family-owned firm, uses AI via its subsidiary Genentech. AI is used in oncology diagnostics and in managing clinical trials, often aided by real-world data from Flatiron Health. Roche supports precise but cautious deployment of AI, focusing on improving oncology treatment (Roche, 2024).

Sanofi and Exscientia use AI for the discovery of small molecules as drugs. Sanofi can spot new candidates and shorten preclinical research timelines using the partnership. Its 2022 report confirms that AI enables strategic R&D capabilities (Sanofi, 2022).

AstraZeneca collaborates with BenevolentAI for target identification through disease modeling. Their use of AI varies from research to real-world evidence, enabling adaptive clinical protocols and precision recruitment to trials (AstraZeneca, 2022).

Bayer's pharmaceuticals business works with Recursion Pharmaceuticals on AI-driven genomics and phenomics. It also has internal AI departments that offer drug response predictions and optimize production systems. The application of their AI is strongly oriented toward sustainability and innovation goals (Bayer, 2022).

Boehringer Ingelheim is similarly a family business leveraging AI in target validation, primarily in oncology. The firm has collaborated with Phenomic AI to develop predictive models of tumors. Though privately owned, its reports reveal significant investment in data science capabilities (Boehringer Ingelheim, 2022).

Novartis has incorporated AI into its digital innovation plan through collaborations with companies like Isomorphic Labs. Novartis employs AI for compound screening and has a distinct internal unit focused on digital drug development. Novartis issues regular progress reports, looking back at an open and methodical way to implementing AI (Novartis, 2023).

Novo Nordisk has used AI widely in early-phase development and research. Natural language processing and machine learning software guide internal decision-making and portfolio management. They are embedded in Novo Nordisk's overall automation strategy (Novo Nordisk, 2024).

Takeda has embraced an AI strategy that focuses on compliance with regulation in its MIT-Takeda program. It uses generative AI for preparing regulatory documents and submission planning, reducing internal labor expense and turnaround time (Takeda, 2023).

This overview shows that AI is no longer an experiment wager for these firms, but rather a cornerstone of their innovation strategies. While AI maturity differs, every company studied has a minimum of one reported practical use of AI. These instances affirm that the use of AI in pharmaceutical processes is not only deliberate and strategic but also driven by competitive necessities, regulatory needs, and innovation aspirations.

5.2 Industry Positioning

The evidence of Sections 5.1 and 5.2 is not of a pharmaceutical industry dabbled with artificial intelligence (AI) but one largely defined by it. While the details of rollout vary company to company, what emerges is a clear trend: AI is no longer held to be an investment of the future but a strategic tool of the here and now. Firms that don't engage with AI with seriousness risk falling behind—not just in technological capability, but in clinical effectiveness, investor confidence, and even regulatory efficiency.

Across the 11 firms in the analysis, a stratified pattern of AI adoption is seen. At the top tier are firms like Pfizer and Novartis that demonstrate enterprise-grade digital strategies. These firms integrate AI across R&D, clinical trials, compliance, and post-market monitoring. They reference AI in strategic reports, have in-company data science teams, and enter into long-term partnerships with AI firms. Their disclosures beyond vague language consist of quantifiable goals and timelines. These firms treat AI as a pillar of competitive strength.

In the mid-tier, companies like Amgen, Eli Lilly, and AstraZeneca show high interest in AI but in more functionally selective or pilot-based applications. Their approach is partnership-based, and their application of AI—albeit documented—is characterized as augmentation, not transformation. These companies may be scaling AI initiatives internally, but their use cases today are compartmentalized.

On the lower scale of integration are players like Boehringer Ingelheim and Takeda. These will focus on specialized AI applications, for example, automation of regulation or oncology diagnostics, without corporate transformation. In some cases, this may be due to the private nature of the company (e.g., Boehringer Ingelheim), which can reduce disclosure requirements and investor-driven pressure. In others, such as Takeda, strategic conservatism or risk sensitivity to regulation can explain the narrower AI focus.

Interestingly, the companies that appear most prominently in innovation and investor rankings are also companies that make the most public case for their AI approach. For instance, Pfizer and Novartis appear regularly in third-party benchmarking publications like the IQVIA Digital Maturity Index and McKinsey's Pharma Innovation Scorecard (IQVIA, 2023; McKinsey, 2022). These lists tend to rate companies on digital foundations, talent resources, and innovation output—all factors disproportionately impacted by AI.

A second observation is how AI integration correlates with therapeutic area concentration. Firms that have a high bet in oncology and rare diseases—e.g., Roche, AstraZeneca, and Eli Lilly—have more advanced AI capabilities. It logically follows that this is the case: the sophistication of these therapeutic areas requires mass data analysis and pinpoint targeting, both of which are AI strengths. Firms that have more diversified but lower-data portfolios may utilize AI more cautiously.

A third noteworthy pattern is the strategic use of AI partnerships. While some companies build in-house capabilities, most firms also rely on external collaborations to scale innovation. This hybrid model appears particularly effective, as it allows companies to access niche AI expertise without overhauling internal structures. For instance, Bayer’s partnership with Recursion and Sanofi’s work with Exscientia reflect a pragmatic strategy to accelerate time-to-insight without sacrificing internal control.

But the analysis also reveals some gaps. The vast majority of firms still offer no overt figures for AI ROI (return on investment), operational efficiency, or implementation timelines. Few reference ethics, data bias, or AI governance processes in their outward-facing reports. Such caution may indicate infancy in strategic planning or a conscious decision to avoid overpromising in a space where regulation and outside pressure are evolving rapidly (Accenture, 2021).

AI applications are also beginning to shape reputational narratives. Firms that communicate transparency on their digital investments appear more responsive to ESG goals, particularly on innovation, medicine access, and forward-looking preparation. Institutional investors resonate with

these narratives, as they increasingly integrate ESG considerations into their models of valuation (BlackRock, 2022). Thus, AI strategy is not merely an operating concern—it is increasingly a corporate positioning vehicle in international capital markets.

In general, the pharma sector is at an AI stratification moment. There are companies that are pushing forward with aggressive, end-to-end strategies, while others are playing it safe or working in isolation. It's not necessarily where they are applying AI that makes them leaders, but how they are discussing it—both within and outside. The next chapter will explore how these variations unfold as patterns of strategy and what they're indicating regarding the future of pharma innovation.

6. AI Strategy in U.S. Pharma Analysis

6.1 Tactical vs. Transformative Adoption

In practice, transformative adopters are developing in-house platforms that integrate information across formerly siloed functions. Novartis' 'Nerve Live' platform, for instance, integrates clinical, regulatory, and manufacturing data to facilitate real-time decision-making, with a complete view of development pipelines. Interconnectedness not only propels operational throughput but also supports a responsiveness and agility culture across departments (Novartis, 2023).

Conversely, tactically oriented organizations apply AI in a plug-and-play mode. AI technology is layered on to address stand-alone problems without altering current processes. Perhaps it is because of limited budgets, outdated IT infrastructure, or leadership cynicism. Regardless, it limits the ability to harness compound value from AI over time—what some researchers call 'digital spillover' (Westerman et al., 2014). Organizations in this category seem to revert to the same operational distress without achieving breakthrough gains.
One of the main findings of this study is the division between tactical and transformative AI approaches for U.S.-aligned pharma companies. Tactical uses are characterized by single-use cases—such as recruitment aids for trials or regulatory document automation—whereby AI addresses a specific operational issue. Transformative approaches, by contrast, feature AI as an essential organizational asset, built into enterprise architecture, strategic planning, and long-term innovation pipelines.

Pfizer and Novartis are distinguished by their transformational emphasis. Both utilize AI in a variety of functional domains including R&D, clinical trials, compliance, and pharmacovigilance. More importantly, they tie these efforts to measurable business outcomes and report on progress in formal filings. Both companies have on-site AI labs, recruit data scientists directly, and use AI metrics in executive dashboards. Their approach is similar to what Westerman et al. (2014) have called digital mastery: the convergence of technological depth with leadership commitment.

Conversely, companies such as Boehringer Ingelheim and Takeda show strategic directions. Their AI uses, although existing and often high-value, remain tied to individual processes—such as filing of regulations or maximizing tumor targeting. These uses are often from outside and not usually enterprise-wide digital remakes. This defines the limits of their system-level impact and reflects a more cautious or cost-sensitive digital transformation strategy (McKinsey, 2022).

The divergence has strategic implications. Transformational adopters gain long-term agility and the capacity to reallocate resources rapidly in order to take advantage of future AI breakthroughs. Tactical adopters have operational benefits but may lag behind in systemic performance and positioning. As the pharma sector increasingly shifts towards digital integration as a capability, this divergence may accelerate.

6.2 Internal Development vs. External Partnership

Particularly, whether development is internal or external also influences organizational learning and knowledge retention. Internal development welcomes iterative improvement and enables firms to train models on proprietary datasets, refining specificity and prediction. External partnerships, although rapid, may reinforce knowledge asymmetries, where the external vendors retain important algorithms and data. This creates long-term reliance and stifles innovation autonomy (Chui et al., 2020).

Case studies support this divide as well. Pfizer's internal AI initiative involves closed-loop feedback processes, where outputs from clinical trials directly influence training models to be applied in earlier-stage research. Such closed-loop processes are seldom feasible in externally driven environments, reflecting the competitive edge of internal infrastructure where scale and investment allow.
The second key dimension of difference is the manner in which firms build their AI capabilities: internally or through external partnerships. Pfizer and Novartis are examples of companies exhibiting internal development strategies, with distinct AI units, in-house talent acquisition, and proprietary data streams. Such organizational structures allow for tighter coupling with business processes, customized tool building, and better data stewardship. Internal development reflects belief in the strategic value of AI and allows for long-term accumulation of learning (Chui et al., 2020).

Conversely, Sanofi, AstraZeneca, and Bayer are immensely reliant on external partnerships. Their partnerships with Exscientia, BenevolentAI, and Recursion as examples say a lot of how reliant they are on third-party platforms for innovation delivery. This approach, while reduces the upfront investment and allows for faster launch of pilots, suffers from intellectual property ownership, standardization of data, and long-term fit.

A hybrid approach is emerging, too. Firms can develop in-house AI infrastructure in addition to collaborating with specialist companies on niche tasks or frontier capabilities. Eli Lilly's cooperation with Genetic Leap is an example of such middle ground—outsourcing RNA modeling capabilities but developing internal systems for monitoring trials. This offers adaptability and accelerates innovation cycles but requires solid integration protocols.

Strategically, in-house development is preceded by firms who consider AI as competitive advantage, while external partnership suits others who focus on speed-to-insight and risk management. The choice typically hinges on firm size, leadership steerage, and digital maturity (Deloitte, 2021). Firms with insufficient in-house capability may consider alliances not only convenient, but necessary to be competitive in an increasingly AI-driven sector.

6.3 Framing and Disclosure in Public Filings

Also, disclosure framing affects the relations with the regulators. Firms with transparent AI strategies are in a stronger position to negotiate with agencies like the FDA in terms of future digital health policies. Pfizer's direct engagement in the FDA's pilot programs on software as a medical device (SaMD), for example, is a classic illustration of the way in which policy influence is facilitated by purposeful disclosure. Conversely, firms with opaque disclosures may be excluded from these initial conversations and fail to shape or adjust coming regulations.

Besides investor and regulatory needs, disclosure strategy also helps in the attainment of partnerships. Tech providers and biotech firms prefer well-articulated digital strategies when selecting their pharma counterparts. Well-articulated AI goals, governance frameworks, and data-sharing practices make a firm more trustworthy in such an ecosystem (Deloitte, 2021).
The final but significant point of strategic distinction is that companies reveal their AI strategies through outside reports. This is especially urgent in the American market, in which investor relations, regulatory expectations, and ESG disclosure intersect. Firms like Pfizer, Novartis, and Eli Lilly are getting increasingly precise in the delineation of AI objectives, outcomes, and strategic alliances in 10-K filings and investor presentations. The disclosures include schedules, appropriation allocations, and effect measurements, underpinning the image of digital leadership (Pfizer, 2022; Novartis, 2023).

Other firms, such as Boehringer Ingelheim or Takeda, provide thin insight into their AI activities. While they may engage in high-value applications, these are likely to be framed as exploratory or indirect. Complete reporting could be avoided through a desire to manage regulatory scrutiny, avoid market hysteria, or simply the internal inability to produce detailed disclosures (BlackRock, 2022).

Framing also sets market acceptance. Institutional investors and analysts increasingly demand digital maturity indicators, i.e., AI governance, risk management, and alignment with business outcomes. Firms that frame these in their filings not only gain credibility but are also positioning themselves for favorable capital availability. 68% of pharma leaders in a 2021 Accenture survey reported greater investor interest following open disclosure of an AI strategy (Accenture, 2021).

The message is clear: framing matters. The language that firms use to speak about AI communicates not just their digital savvy but also their governance mind-set and competitive strategy mind-set. As AI becomes more of a mainstream operating technology, disclosure quality can be as crucial as technical adoption in determining leadership in industries.

7. The Role of Regulation, Compliance, and Risk

7.1 Regulatory Influence on AI Speed and Structure

Moreover, the new FDA proposal for a pre-set change control plan for machine learning software has further long-term implications. The plan would allow developers to pre-approve future changes to the algorithm if they are within a pre-set scope and get tested post-deployment. For pharma firms, this will help to bring significant relief in administrative overhead and time-to-market for AI solutions with adaptive changes. Yet it also demands that firms create specific, traceable procedures for tracking algorithms—a task that requires close collaboration between technical teams, regulatory affairs, and third-party auditors (FDA, 2023).

The influence of the data minimization requirement under HIPAA cannot be overstated either. Though meant to manage overreach in utilization of patient information, it imposes prohibitive complexity on the training of AI platforms. Drug companies consistently find that once identifiers are taken out and access entitlements fragmented, what remains is not of the detail needed for high-risk clinical inference. Consequently, some businesses now lobby for new regulatory guidance on de-identification procedures that would preserve analytical value as well as uphold privacy standards.
Artificial intelligence (AI) within the US drug sector operates in one of the global world's most complex regulatory frameworks. Two of the strongest regulatory bodies—the Food and Drug Administration (FDA) and the Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA)—have an effect not only on the technical design of AI solutions but even on their deployment tactics.

The regulation of the FDA is central to understanding how drug companies utilize AI. As part of its broader program to promote digital innovation, the FDA issued a series of guidance documents under the Digital Health Innovation Action Plan (FDA, 2023). These include approaches for evaluating software as a medical device (SaMD), adaptive clinical trials, and integration of real-world evidence (RWE). While such efforts facilitate the deployment of AI, they also necessitate robust validation procedures, openness of algorithmic decision-making, and ongoing monitoring of performance.

The regulations typically impede AI adoption in high-risk use cases, such as clinical decision support tools or diagnostics created with AI. These tools must meet the FDA's significant evidence threshold and receive periodic reviews. For this reason, pharma companies have a tendency to limit AI use in clinical functions unless backed by mature digital health vendors that can offer these standards.

HIPAA's role in the adoption of AI is no less significant, more so in patient data usage. HIPAA requires that all patient-identifiable data used by AI algorithms must be anonymized, encrypted, and comply with data access policies. Such restrictions, though required to maintain the public's confidence, complicate the deployment of AI models that have been trained with real-world data such as EHRs or genomic sequences (HHS, 2022). Businesses must develop secure cloud platforms and data-sharing systems that are compliant with HIPAA, which tends to slow down the deployment of AI technologies.

Even with such problems, regulatory insight also allows for strategic planning. Firms like Novartis and Pfizer have developed special compliance divisions that work closely with digital teams to ensure all AI initiatives are up-to-code with evolving FDA and HIPAA regulations. Coordinating regulatory vision with innovation planning gives a competitive advantage, as such companies become early implementers of FDA pilot schemes and influence the shaping of future policy development (Pfizer, 2022; Novartis, 2023).

7.2 Legal Boundaries and Compliance Practices

One of the most impressive examples of regulatory anticipation is the creation of AI ethics advisory boards in pioneering companies. These boards, usually consisting of ethicists, technologists, lawyers, and patient groups, consider proposals for deploying algorithms to determine their potential effects on society. Bayer and Sanofi are among companies that have included such a review process in their R&D approval process, improving regulatory credibility with overseers as well as outsiders (Sanofi, 2022; Bayer, 2022).

Secondarily, global harmonization is a concern. While U.S. firms face primarily FDA and HIPAA, multinational firms must also deal with GDPR, Canada's PIPEDA, and Japan's APPI. As additional AI solutions are implemented internationally, drug firms are creating compliance dashboards that harmonize varied jurisdictional requirements, reducing legal uncertainty. Such proactive behavior improves not only compliance but also makes regulatory filings simpler and faster global rollouts.
Compliance in AI adoption extends beyond legislated compliance to encompass ethical regulation and risk management. AI algorithms, particularly those used in patient-facing scenarios, pose new risks such as bias, inaccuracy, and unexplainability. Pharmaceuticals are therefore adopting formal compliance procedures that incorporate control into every phase of AI development.

Most companies have adopted AI governance frameworks that include validation processes, ethics review panels, and interdepartmental oversight boards. The models are founded on Good Machine Learning Practice (GMLP) guidelines and are aligned with existing pharmaceutical quality assurance standards (Deloitte, 2021). With the use of clinical-grade audit trails and automated model diagnostics, companies ensure that AI solutions are not only safe but also explainable and responsible.

Different companies also publish ethical AI standards as part of their ESG reports. For example, Eli Lilly has committed algorithmic transparency and fairness in its clinical trial recruitment technology. AstraZeneca has also reported putting data bias detection layers into its predictive trial simulations to reduce demographic biases (AstraZeneca, 2022; Eli Lilly, 2022).

Legal teams increasingly engage with AI strategy, particularly when software is classified as a medical device. These teams collaborate with technical staff to review assumptions of the models, test data used for validation, and the performance benchmarks. This engagement is required to avoid post-market compliance failures, which result in regulatory sanctions, investor opposition, and loss of public trust (FDA, 2023).

Apart from internal procedures, companies also employ third-party certifiers and attorneys to assure conformity before AI software becomes available on the market. Pre-implementation auditing is now standard in co-operations between pharma sponsors and AI startups so that liability and data protection is understood across both parties.

7.3 Data Privacy and Innovation Strategy

One of the innovative solutions to governance of privacy is homomorphic encryption—a cutting-edge cryptographic technique that allows for data calculation without decryption. Pfizer and Roche tested this method in oncology trials to protect patient data while comparing treatment outcomes between

different sites. Though computationally intensive, it offers a path forward for scale-friendly analytics with privacy (Pfizer, 2022; Roche, 2024).

Strategically, privacy frameworks also affect AI architecture. Businesses are rearchitecting model architecture in terms of modularity so that sensitive inputs can be isolated or substituted without retraining entire systems. This reduces compliance risk while retaining flexibility. At the same time, businesses are increasingly involving patients in data governance. Several businesses have launched opt-in digital consent platforms that allow individuals to monitor how their health data is being used in AI research, increasing transparency and long-term trust.
Privacy of data is one of the strongest extrinsic drivers of AI innovation strategy in the pharmaceutical sector. The industry is based heavily on patient-level information—clinical trials, EHRs, and genomic studies—to train and deploy effective AI systems. Yet strong privacy laws, led by HIPAA in the US and GDPR globally, force corporations to balance innovation with severe protection mechanisms.

This tension has resulted in a conservative stance toward experimentation with AI. For instance, real-time patient monitoring or personalized treatment suggestions using AI are technologically feasible, but fewer companies have operationalized them at scale due to privacy concerns. Legal mandate for de-identification and encryption of health data constrains the breadth of training data, potentially curtailing model accuracy and generalizability (HHS, 2022).

Companies have invested subsequently in machine learning that protects privacy, synthetic data creation, and federated learning in a bid to build AI models without being given direct access to raw data. This keeps privacy intact while analytics remain uninterrupted. Novartis and Roche, for example, have been engaged in rolling out federated learning frameworks on their global trial data without breaching confidentiality for patients (Roche, 2024; Novartis, 2023).

Strategically, businesses are now including privacy by design within their digital strategy. That is, collaboration between compliance, legal, and engineering teams at the design phase and not an afterthought. It also involves external certification and public outreach initiatives to assure stakeholders of the company's ethical stance.

Finally, privacy compliance is becoming a source of competitive strength. Organizations that can demonstrate robust privacy safeguards for AI activities are more likely to obtain regulatory clearances, form strategic partnerships, and maintain brand trust. As AI becomes more advanced and ubiquitous, data privacy will be both a limiting factor and an accelerator—limiting some possibilities while compelling the industry to act more responsibly.

8. Discussion: AI Adoption Challenges and Enablers

8.1 Synthesis of Case Study Findings

In addition, AI adoption is being used by certain companies as a source of organizational rejuvenation. Digital initiatives are increasingly becoming drivers of internal change, simplifying legacy processes, and challenging departments to become more data-driven in their decision-making. At companies like Eli Lilly, AI adoption in clinical trials has led to broader changes in regulatory affairs and

pharmacovigilance activities, demonstrating how innovation in one function can spur change across the value chain (Eli Lilly, 2022).
Chapter 5's case studies illustrate a mature and multi-level adoption of artificial intelligence (AI) within U.S.-based pharmaceutical behemoths. While all 11 companies covered have adopted AI to some degree, their adoption strategies, functional focuses, and strategic positioning are quite heterogeneous. Leaders like Pfizer and Novartis oversee AI as a cross-enterprise innovation driver, with extensive investments in capability building internally, open publication, and multi-functional integration. Alternatively, firms such as Boehringer Ingelheim and Takeda adopt a narrower, more tactical approach, applying AI for isolated problems like regulatory submissions or oncology diagnosis without enterprise-wide change.

A definite pattern that emerges is the alignment of AI strategy, organizational culture, and resource configuration. Firms with high digital literacy, strong leadership buy-in, and mature infrastructure pursue transformative AI initiatives. These firms tend to use AI in diverse functions—R&D, manufacturing, compliance—and build in-house AI capabilities. In contrast, those with legacy systems, conservative management, or limited talent pools restrict AI adoption to small-scale pilots or outsourced functions. These variations are reflective of underlying strategic priorities and risk appetites.

8.2 Success Enablers of AI Integration

Organizational culture is another informal enabler. Businesses that have an experimental culture—encouraging pilot projects, tolerating failure, and rewarding cross-disciplinary collaboration—are more likely to be effective with AI tools. That kind of cultural orientation reinforces iterative learning and maintains AI as an adaptive, evolving capability rather than a fixed investment. Case studies suggest that culturally agile businesses can scale AI faster by codifying learning from a single project into standards for broader application.
The research identifies four key enablers that consistently drive successful AI adoption in pharma firms: leadership alignment, digital infrastructure, access to capital, and collaborative ecosystems.

First, executive-level buy-in is critical. Those organizations that have C-suite champions of AI and established data governance committees are more agile and directed at introducing AI solutions. Leadership provides not only funding and visibility but also continuity of strategy. Pfizer's committee on digital transformation, for instance, governs the introduction of AI into all aspects of operations (Pfizer, 2022).

Second, robust digital infrastructure—e.g., cloud-based data lakes, interoperable databases, and secure analytics platforms—is essential. Firms like Novartis have created enterprise-wide digital architectures that enable AI scaling and data integrity (Novartis, 2023).

Third, access to capital enables long-term investment in proprietary AI labs, training programs, and pilot initiatives. Publicly traded firms allocate a portion of R&D budgets to digital innovation, illustrating investor appetite for future-readiness.

Finally, partnerships with tech firms, research labs, and AI startups offer critical knowledge transfer and speed-to-insight. Collaborations such as Sanofi’s with Exscientia or AstraZeneca’s with

BenevolentAI exemplify how external expertise accelerates internal transformation while mitigating risk (Sanofi, 2022; AstraZeneca, 2022).

8.3 Barriers to Scalable AI Use

Fragmentation of data ownership also causes friction. In multinational pharma companies, data resides in regional silos that are under local compliance laws, and it's hard to train AI systems that require cohesive data streams. Without access to harmonized data, even AI initiatives amply provided with capital get stalled for want of scale or quality of input data.

Moreover, internal resistance by employees—particularly those whose tasks can be augmented or replaced by automation—can impede adoption. Change management processes often are immature, creating low morale or resistance to buy-in. Organizations that address these cultural tensions early, with retraining programs and internal communications, fare better in implementation.
Despite mounting hype around AI, there are significant obstacles. Leading among them are legacy systems, regulatory complexity, and talent shortages.

Legacy IT infrastructure—dominant in established pharma firms—hinders data unification and model deployment. To integrate disjointed systems, costly integration layers are required, delaying or complicating AI implementations. Firms like Bayer and Boehringer Ingelheim refer to challenges in standardizing production and research databases across multiple global sites (Bayer, 2022).

Regulatory uncertainty also dissuades ambitious experimentation. Organizations hold back from bringing AI to high-stakes areas without clear FDA or HIPAA guidelines, especially for adaptive algorithms or real-time monitoring systems. While pilot programs are underway, end-to-end frameworks remain underdeveloped.

Finally, the paucity of AI talent with domain expertise as well as technical skills slows down program expansion. While partnerships plug gaps in the short term, firms lacking internal capability struggle with continuity of AI initiatives over the long term. Internal resistance to change and a lack of upskilling infrastructure compound these problems.

8.4 Implications for Innovation Management and Organisational Behaviour

We also witness the interaction between AI efforts and organizational identity. Companies that style themselves as digital leaders—e.g., Novartis and Pfizer—also deal with AI in terms of strategic narrative. This kind of framing is followed by internal alignment around digital agendas and hiring of digitally experienced talent. By integrating AI into corporate narrative, these firms render digital transformation a persistent strategic theme rather than a passing initiative.
The patterns herein are aligned with key organizational behavior and innovation management principles. Firstly, the distinction between exploratory vs. exploitative innovation—framed by March (1991)—is evident. Changed firms search for new competencies and redesign processes to accommodate AI, while tactical adopters exploit existing structures through incremental improvement.

Second, the role of absorptive capacity, as formulated by Cohen and Levinthal (1990), is evident in how companies absorb external knowledge from collaborations. Pfizer or AstraZeneca are examples of high absorptive capacity companies that internalize knowledge from AI collaborators well, while others are unable to translate collaborations into sustainable internal capability.

Thirdly, organizational ambidexterity is accountable for operational efficiency and innovation balancing. Firms that possess compliance and frontier AI together—such as Novartis—exhibit dynamic capabilities. They reconfigure processes, re-skill people, and develop flexible infrastructure to change rapidly (Teece, 2007).

Cumulatively, these theories help to frame AI adoption not as a purely technical issue but as a strategic, cultural, and organizational transformation. Firms that embed AI within these overall management frameworks are well-positioned to lead the next wave of pharmaceutical innovation.

9. Conclusion and Recommendations

9.1 Summary of Research Design and Findings

The thesis began with a quantitative scan of close to 400 pharmaceutical companies from a structured Stata dataset. The aim was to map the degree of AI uptake in a broad industry sample. However, despite the initial ambition, only a small sub-sample of these companies—a total of 11 —met the strict inclusion criteria for detailed examination. The criteria required direct, verifiable evidence of AI uptake extracted from regulatory filings, annual reports, or official announcements.

This narrowing of the dataset does not weaken but strengthens the empirical robustness of the thesis. By filtering for document-supported, high-confidence cases, the analysis avoids speculation and concentrates on verifiable corporate actions. The remaining firms in the expanded dataset did not announce AI adoption or lacked sufficient public transparency, which is itself a noteworthy industry result. Thus, the study transitions from a quantitative starting point to a qualitative deep dive, offering a close-up view of best practices and strategic directions in AI adoption.
This thesis has investigated the application of artificial intelligence (AI) among U.S.-based pharmaceutical firms, offering an extensive empirical study grounded in company reports, public filings, and scholarly literature. The study tracked, across nine chapters, the application of AI in research and development (R&D), clinical trials, manufacturing, regulatory compliance, and patient monitoring, and uncovered main trends in adoption strategy, firm structure, and market dynamics.

The main conclusion is that AI adoption in the pharma industry is genuine but skewed. Of the several dozen companies researched initially, only a handful—11 in total—provided documented, verifiable evidence of AI adoption. The firms differ not only in where they're applying AI but also in how they discuss it. Some, such as Pfizer and Novartis, are trying enterprise-wide transformations, infusing AI into their corporate DNA. Others, like Boehringer Ingelheim and Takeda, use AI more tactically, leveraging it to address specific bottlenecks or regulatory pain points.

The thesis identifies enablers such as executive leadership, digital infrastructure, capital investment, and collaborative ecosystems. These undergird transformational AI initiatives. Conversely, inhibitors are fragmented legacy systems, regulatory uncertainty, data privacy, and talent shortage. These

findings suggest that AI success is not simply a function of budget or access to technology, but a function of organizational readiness, strategic clarity, and cross-functional alignment.

The role of regulation—especially by the FDA and under HIPAA—seems a double-edged sword. On one hand, onerous regulatory regimes retard deployment in sensitive applications. On the other, they offer clear guidelines that reduce strategic uncertainty. Leading firms are not those that avoid regulation, but those that address it proactively, engaging in pilot plans and building internal compliance capabilities. The majority of innovative companies treat regulation as a design constraint to operate inside, rather than an obstacle to circumvent.

This thesis also makes a contribution by closing the gap between corporate reality and innovation management theory. Dynamic capabilities, absorptive capacity, and organizational ambidexterity are all defined in the practices of firms that successfully scale AI. For instance, the ability to absorb external knowledge from AI partners—while developing internal capabilities—tightly adheres to innovation diffusion theory as well as learning organization theories.

One of the meta-findings is the strength of strategic framing. Companies that most clearly articulate their AI strategies—through investor filings, ESG reports, and public partnerships—seem to attract more investor confidence, talent, and collaboration opportunity. This suggests that transparency is not only a compliance function but a strategic lever in its own right.

At the industry level, the pharmaceutical sector appears poised for AI disruption across segments like adaptive trial design, real-time pharmacovigilance, and precision medicine. However, the unevenness of adoption and concentration of expertise in a handful of firms can exacerbate competitive imbalances. Smaller or risk-averse firms may fall technologically and strategically behind over the coming years.

From a policy perspective, regulators have the opportunity to accelerate responsible AI adoption by providing harmonized principles, sandboxes, and public-private cooperation. Policy gaps—particularly on real-time AI iteration and global data sharing—need to be addressed to enable more widespread adoption without compromise to ethical and clinical standards.

In conclusion, AI in pharma is no longer optional. It is ever more at the heart of how innovation is conceived, executed, and evaluated. Companies that fail to develop coherent AI strategies risk obsolescence—not simply in operational efficiency, but in market relevance. For corporate leaders, the path forward requires not just investment, but integration. For researchers, this thesis offers a blueprint for further exploration of AI's organizational implications. And for policymakers, the findings underscore the importance of adaptive, forward-looking regulation that keeps pace with technological possibility.

Future research may be longitudinal in nature—examining AI performance outcomes over time—or cross-industry comparative in nature to determine whether pharma dynamics are similar in other high-complexity, high-regulation industries. A third avenue of research would be an examination of the ethical implications of AI in pharma on the patient side, especially in areas like algorithmic bias, data consent, and AI-aided diagnostics.

Last but not least, this thesis reaffirms that AI is not a tool; it's a transformation. And like any transformation, its success depends as much on people and process as on technology.

9.2 Strategic and Theoretical Implications

This thesis contributes to the broad field of innovation management by confirming that strategic clarity, organizational agility, and leadership alignment are good predictors for AI adoption success. The case studies from the real world nicely fall into theoretical frameworks like March's exploration vs. exploitation, Cohen and Levinthal's absorptive capacity, and Teece's dynamic capabilities. For example, firms like Novartis demonstrate ambidexterity—trade-offs between regulatory stability and digital experimentation—whereas Pfizer demonstrates high absorptive capacity through its internal AI development pipeline.

Crucially, these observations suggest that the adoption of AI cannot be confined to IT departments. Instead, it must be embedded within strategic planning, talent management, and governance systems. This is what organizational behavior research attests to as well, noting that firms with cross-functional collaboration and open internal communication are better able to absorb new technologies. To that extent, pharma's AI future rests as much on behavioral change as on technical sophistication.

Further, the pattern of adoption observed here strengthens the fact that AI is a strategic variable—a driver that configures and is configured by organizational purpose. Those corporations that consider AI as a means to differentiation—rather than just cost reduction—experiment more aggressively and realize network effects more quickly. This supports the theory of open innovation, which states that companies are increasingly dependent on external knowledge flows to achieve internal innovations (Chesbrough, 2003). The pharmaceutical industry, with its emphasis on collaborative science and regulatory compliance, is perfectly positioned to take advantage of this synergy.

Last, the thesis surfaces new directions for organizational learning in the age of AI. The traditional frameworks were centered on feedback loops based on market or operational outcomes. Here, AI shifts the locus of learning to predictive analytics and real-time data feeds. Firms with dynamic learning systems—those capable of ingesting algorithmic feedback—demonstrate improved decision-making. It is this attribute that will define competitive advantage as pharma shifts toward more adaptive, decentralized innovation ecosystems.

9.3 Recommendations and Future Research Directions

This research supports several future-oriented recommendations. First, pharma firms have to invest early in AI governance frameworks—embedding legal, ethical, and technical oversight within broader compliance systems. Second, firms have to view partnerships not just as outsourcing mechanisms but also as learning opportunities. Insertion of external expertise through co-location or staff secondments can create internal capability.

Third, digital strategy must be accompanied by change management. As AI tools begin to impact workflows, firms must prepare employees by upskilling and communications initiatives. Fourth, regulatory engagement must be proactive. Participation in sandbox programs and submitting adaptive trial designs can enable firms to learn early and influence policy creation.

Future research can build on this study by tracking AI adoption performance effects over time. For example, do AI-adopting firms achieve faster drug approvals or lower R&D costs in the long term? Longitudinal study designs, perhaps using panel or matched comparison data, would offer greater

causal inference. Comparative studies across geographies—especially in Europe and Asia—would test whether these findings hold in other regulatory and market contexts.

Fifth, digital maturity audits must be embedded in strategic audits. Just as firms track financial health or operational efficiency, they must now track progress in AI uptake—on the basis of standardized KPIs such as model accuracy, speed of deployment, and time-to-insight. These metrics can guide reinvestment decisions and expose areas that need intervention.

Sixth, there needs to be more focus on explainable AI (XAI) solutions, particularly in regulatory and clinical applications. Transparent algorithms not only minimize compliance failure risk but also establish clinician trust and patient safety. Strategic investment in model interpretability will become mandatory as AI tools transition from supportive to decision-influencing roles.

Finally, future studies should address ethical dilemmas introduced by AI. Topics such as algorithmic bias in patient recruitment, lack of transparency in proprietary models, and the impact of AI-driven job displacement remain underdeveloped topics. Researchers and policymakers should develop frameworks that do not permit innovation at the cost of fairness, transparency, or public trust.

10. References and Appendices

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