ADOPTION OF ARTIFICIAL INTELLIGENCE IN DRUG DEVELOPMENT WITHIN PHARMACEUTICAL INDUSTRY

by

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Dedication

This dissertation is dedicated to my family especially to my beloved father late Dr. Dilip Narayan Bawachkar, (MBBS, DVD) who always inspired me and always there with me forever and ever in all circumstances to pursue my dreams.

No one can stop you once you decided to grow.

Wabi-Sabi !!!!

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ABSTRACT

ADOPTION OF ARTIFICIAL INTELLIGENCE IN DRUG DEVELOPMENT WITHIN PHARMACEUTICAL INDUSTRY

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2025

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The pharmaceutical industry now experiences major changes in research and innovation because Artificial Intelligence (AI) was introduced into drug development processes. The main objective of this research is to present in-depth information about how artificial intelligence (AI) modifies drug development procedures. This research investigates how independent variables affect the relationship between variables leading to the adoption.

The study examines independent external variables’ substantial influence on AI's adoption and integration in drug development. Regulatory frameworks, navigating the balance between innovation and compliance, play a pivotal role. An understanding emerges of regulatory authorities recalibrating guidelines to accommodate AI-driven methodologies. Market dynamics and competitive pressures amplify AI's importance, prompting organizations to embrace AI for sustainable growth and competitive edge. Patient-centric imperatives underscore AI's potential to drive personalized medicine, optimize clinical trials, and enhance patient outcomes.

Internally, organizational culture shapes AI assimilation, influencing the readiness to adopt innovations. Technical infrastructure and financial resource allocation determine AI integration feasibility and scope. The review highlights AI's potential to foster novel collaboration models and cross-functional synergies within organizations.

The literature review led to the development of an appropriate conceptual framework for this research. The research adopted a quantitative approach for its design. For this research the chosen tool was a questionnaire. The questionnaire contained 24 non-demographic questions rated on a five-point Likert scale and was distributed to the relevant participants. The survey obtained 306 responses from the 1500 participants achieving a final response rate of ~ 21%. This participant group contained professionals from both the pharmaceutical industry and AI technology who represented international expertise. Software package ADANCO 2.4 enabled analysis of variance-based structural equation modelling to develop model hypotheses. The framework achieved complete success in reliability and validity assessment measures. The analysis revealed significance in nine hypotheses created to explain direct relationships and indirect relationships between variables. Surveys with demographic data were distributed to pharmaceutical organizations throughout the world.

The research findings indicate that artificial intelligence markedly improves the efficiency and effectiveness of drug development processes, especially within data-driven contexts. However, effective deployment involves a high level of organizational agility and culture, and market landscape and dynamics. Ethical considerations and regulatory frameworks serve as challenges to implementation, underscoring the necessity for a strong technological infrastructure and systemic restructuring to utilise big data efficiently. Organisational agility, influenced by data standards and a culture focused on innovation, is a critical element in the adoption of AI solutions.

Market dynamics significantly influence AI readiness, highlighting digital adoption as an essential competency for modern pharmaceutical organisations. The findings highlight the potential of AI to transform drug discovery, depending upon companies effectively addressing critical challenges associated with data privacy, feature selection, and regulatory compliance. This research provides practical insights for aligning organisational strategy with technological innovation to achieve successful adoption of AI.

The study revealed essential understanding regarding AI adoption within pharmaceutical drug development operations. Research findings function as an initial reference point to connect research areas while recognizing essential factors within Pharma industry operations in AI-driven drug development. This research established an explanatory model which pharmaceutical industry users can utilize to resolve their issues or foresee potential barriers in implementing AI effectively.

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Chapter 1: Introduction

1.1 Introduction

The current chapter provides an overview of available researches within the current body of knowledge as well as core areas with a view of establishing core interest of the research. This section covers the scope of study and also the research problem established. This section will define research aims objectives and purpose of the study. This section will be followed by explanation of the significance of the research.

1.2 Research Background and Scope

Healthcare needs the pharmaceutical sector to achieve vital medical breakthroughs for developing lifesaving therapies. Artificial intelligence has been one of the major drivers of change due to the new opportunities that it presents to boost efficiency alongside cost-cutting and faster development of drugs. Drug development, predictive models, clinical trial logistic optimisation, and precision medicine Artificial intelligence has proven its utility globally in drug development, predictive modelling, optimisation of clinical trials, and precision medicine (Agrawal, 2018).Nonetheless, its implementation in India - a rapidly developing centre for pharmaceutical innovation - remains in its infancy, impeded by distinct difficulties including resource limitations, regulatory intricacies, and the sector's customary dependence on old research and development methodologies (Sharma, 2021).

The Indian pharmaceutical industry, recognised for its affordable generics and robust manufacturing prowess, is positioned to harness. AI technology to transition from incremental innovation to groundbreaking advancements Applications of AI can eliminate bottlenecks in the drug development pathway and can contribute to faster discovery of potential therapeutic candidates, lowering time-to-market, and reducing overall research and development expenses. Furthermore, India's abundant scientific expertise and expanding digital infrastructure provide a conducive environment for the incorporation of AI into pharmaceutical operations (Sultana et al., 2023).

The current research article explores the drivers surrounding adoption of AI in the Indian pharmaceutical industry, to identify the drivers and the impediments at the organisational, technical, and legal levels. The proposed research will help explain the impact of AI implementation on drug development outcomes providing practical solutions to policymakers and industry players as well as technology suppliers. The study offers an in-depth analysis of the use of AI in the early stages of drug development, the preclinical trial and clinical trials in India, hence addressing a gap within the academic field and the practice of industry.

1.2.1 Pharmaceutical Industry

The Indian pharmaceutical sector stands as a worldwide leader because it manufactures affordable generic drugs while also producing vaccines. The Indian Pharmaceuticals industry establishes itself as a leading sector in worldwide pharmaceutical operations (Kimta & Dogra, 2024) demonstrating its power to shape the international market. The pharmaceutical market in India plans to expand its worth to $65 Bn by 2024 as it aims to achieve $130 Bn revenue by 2030. The pharmaceutical industry of India reaches $50 Bn in present market value while supplying pharma products to more than 200+ countries through its global exports (Kumar et al., 2022).

Research shows that pharmaceuticals produced in this country constitute 10% of worldwide manufacturing capacity and 2% of global market shares. The pharmaceutical sector in this country produces 10% of worldwide pharmaceuticals along with 2% of world market share. Significant improvements in infrastructure development and technical capability lead to the manufacturing of various pharmaceutical products according to Karunakar (2016).The industry currently manufactures bulk drugs across all major therapeutic categories. The organisation possesses a substantial workforce with technical expertise in process development and downstream processing. The capital investment amounts to approximately US$ 4.1 billion. In 2008, the production of bulk drugs reached a value of US$ 3.5 billion, while the formulations generated a worth of US$ 15.4 billion. The growth rate of bulk drugs has been approximately 14%, while formulation has increased by 24% during the 1990s. Modern research development and investigation projects receive increasing attention from investors. It sustains employment for 29 million people through its pharmaceutical manufacturing sector. The pharmaceutical industry plays a role of 2% in India's GDP while generating 12% of the manufacturing sector's GDP (Sindkhedkar et al., 2020).

The pharmaceutical sector of India produces the third-highest quantity globally where generic pharmaceuticals and vaccines together build a substantial manufacturing footprint. Multiple pharmaceutical companies in this landscape combine to make the region a substantial force within worldwide healthcare sector operations. Since Husain published his findings in 2015 the Indian pharmaceutical sector has witnessed remarkable development which shows progress in research methods and manufacturing operations. This sector has achieved a crucial role in worldwide healthcare initiatives by delivering high-quality pharmaceutical products to multiple nations through its history of evolution. The industry produces worldwide healthcare effects which fundamentally shape global healthcare systems (Kaplan & Laing, 2020; Zikmund et al., 2013).

India meets more than half of Africa's generic medicine needs and at least forty percent of the generic pharmaceutical requirements in the United States while supplying twenty-five percent of all pharmaceutical products throughout the United Kingdom. India fulfils more than 60% of all worldwide vaccinations and serves as the leading manufacturer of DPT and BCG and measles vaccines. India supplies 70% of vaccines that the World Health Organization needs according to its essential immunisation schedule. About 60% of vaccine manufacturing takes place in India which designates it the world's leading producer of vaccines. India holds a leading position in international low-cost vaccination production and stands as the biggest producer of generic pharmaceuticals controlling 20% of global pharmaceutical sales (Chatterjee et al., 2021).

New pharmaceutical industry advances emerged through innovative technology advancements throughout the previous years. Artificial intelligence represents one of the modern breakthroughs that shows potential to revolutionize all operations.

Organisational competitiveness and environmental adaptability depend heavily on integrating this technology (Das et al., 2021).

1.2.2 Artificial Intelligence:

Indian pharmaceuticals have access to an industry-transforming potential through embracing artificial intelligence solutions in their sector. AI technology will completely revamp pharmaceutical operations through improvements in drug development together with manufacturing improvements as well as better quality control. Modern machine learning techniques combined with data analytic systems decrease both resource requirements and developmental time in identifying new pharmaceutical medicine candidates (Nagaprasad et al., 2021).

This will speed pharmaceutical development and provide tailored treatment options via precision medicine. Artificial intelligence (AI) in pharmaceutical production enhances operational efficiency, accuracy, and development. AI technologies like predictive maintenance will help reduce idleness and optimise resource allocation. Integrating AI with robotic automation and smart manufacturing systems offers data integration, fast decision-making, and increased production flexibility (Mak & Pichika, 2020).

Artificial intelligence application in assurance and quality control is essential. AI uses machine learning to detect vulnerabilities early and computer vision for real-time process monitoring. While AI deployment has numerous benefits, the pharmaceutical industry faces challenges such as limited resources, labour competence, data security concerns, and complex regulatory frameworks. Clear standards and ongoing advancement are crucial due to ethical issues and the dynamic nature of technology (Hogendroff, 2020). To accomplish effective integration in the pharmaceutical industry, coordinated efforts are needed to provide resources for training, infrastructure, reforming legislation, and recruitment and training. A responsible and productive use of artificial intelligence (AI) requires this strategy (Singh & Lamba, 2021).

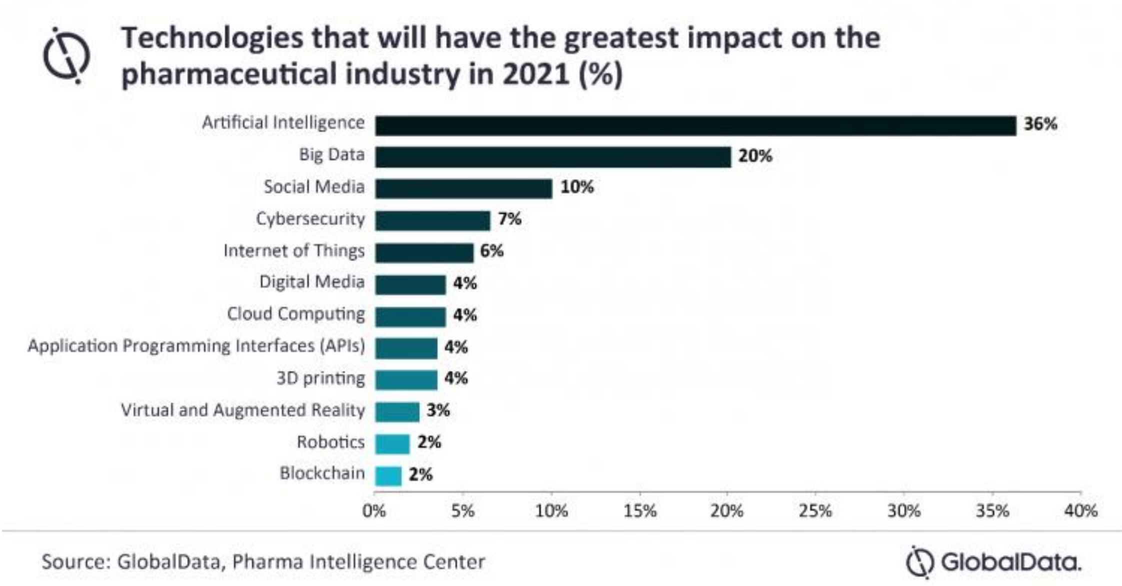


Figure 1: Top 20 Technologies in Pharma (GlobalData, Pharma Intelligence Center, 2021)

A GlobalData evaluation demonstrates how AI technology will transform pharmaceutical business operations through process optimization throughout all pharmaceutical production stages in the next few years. According to the analysis of 198 pharmaceutical experts AI systems were predicted to bring the largest impact on the industry by 36 percent of respondents. Big Data became part of the social media and cybersecurity along with the Internet of Things leading as the most influential transformations in the field of the pharmaceutical sector. As shown in Figure 1, artificial intelligence is one of the main features of pharma industry (EP News Bureau 2021).

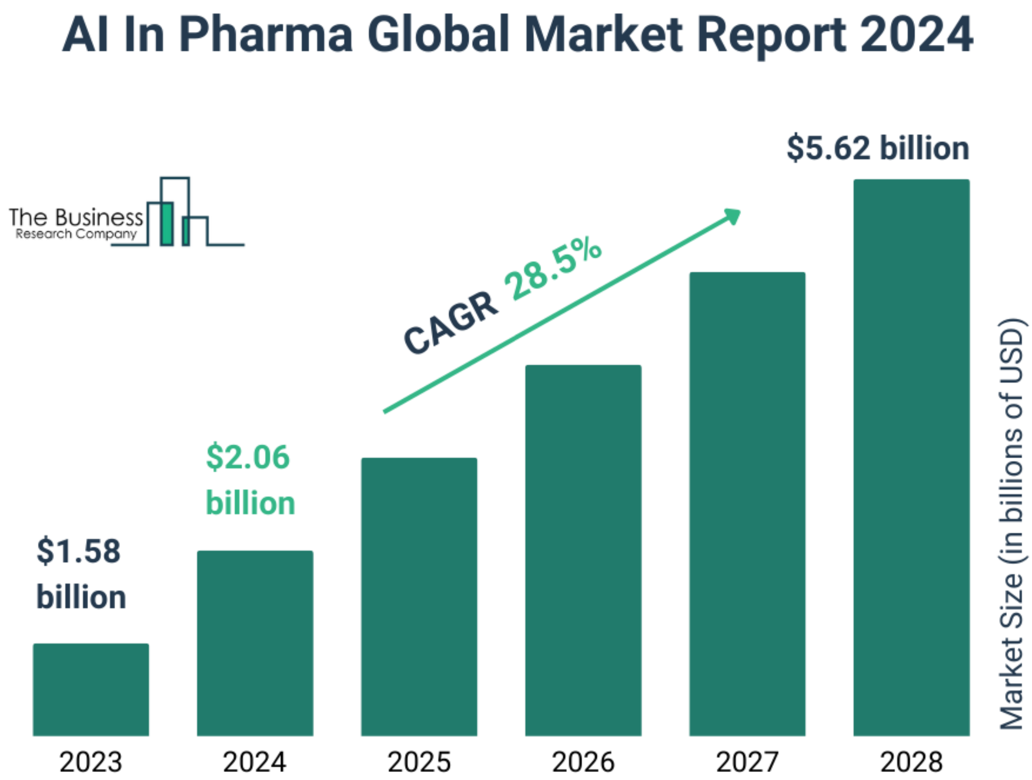


Figure 2: AI in Pharma Global Market (The Business Research Company, 2025)

The pharmaceutical industry has experienced major growth in artificial intelligence market size during recent years. The market value of AI in pharmaceuticals shows accelerating growth with a projected 30.4% compound annual growth rate. It will transform from $1.58 billion in 2023 to $2.06 billion in 2024. In the past, the market grew not only under the influence of the broader use of artificial intelligence (AI) in the field of drug development to increase its efficiency but also because of using AI in the radiographic practice. As illustrated in Figure 2, according to this study by Ali et al. (2024) the AI pharmaceutical market size will experience a lively growth in the coming years. The forecast of AI in Pharma market is that in 2028, it will reach $5.62 Billion with an A CAGR of 28.5 greatly (The Business Research Company, 2025).

The research and development of new pharmaceuticals is characterised by significant challenges, high costs, and extended timelines. The average lifespan of the research and development process is estimated at 10-15 years. Pharmaceutical industry still strives to create the next blockbuster drug regardless of the enormous amount of money that is being spent on it (Fokunang & Fokunang, 2022).

The rate of success in the research and development process is also quite low, with only 1 over 10 possible drugs candidates that manage to pass phase I of clinical trials and get regulatory approval. The technological constraints of the development process of new therapeutic compounds that include financial and time frame restrictions might impact on the integration of AI by the pharmaceutical industry (Kim et al., 2020).

Strategies and technologies employed by AI are relevant to the identification of hit and lead compounds efficiently, in drug target validation, and optimization of drug structure design. This has the potential to benefit the pharmaceutical sector by decreasing the costs and timelines involved in the discovery of novel molecules. Nonetheless, in spite of these benefits, AI continues to face considerable challenges related to data, such as its complexity, growth, diversity, and ambiguity (Arabi, 2021).

AI has promising futures in pharmaceutical discovery and formulation (Gerhard Hessler et al., 2018). With the continued advancement and improvement of artificial intelligence, it is expected that it will be of more significance in drug development. This technology will help researchers identify new therapeutic targets, comprehend drugs interactions, and identify populations of patients who will most likely benefit from certain therapies (Kiriiri et al., 2020).

Drug discovery employing artificial intelligence techniques started its development during the 1960s era. AI has been operational in multiple phases of drug development since its inception in the 1960s starting from target identification through lead optimisation to drug design((Mouchlis et al., 2021). Pharmaceutical development receives assistance from artificial intelligence throughout all drug discovery development stages and formulation optimization processes. (Mahjoub, 2023). This will result in enhanced efficiency and specificity in drug development, as well as advancements in personalised medicine (Blanco-González, 2023).

AI-driven technologies are projected to accelerate the shift towards personalised medicine, addressing patient requirements and promoting global competitiveness.

The combination of historical export data and projected AI/data analytics impacts indicates a promising future for the Indian pharmaceutical business, indicating efficiency, innovation, and global relevance (Kim et al., 2020).

1.3 Significance of the Study

New drugs development carries high risks and the possibility of considerable gains. The drug development success rate is remarkably inadequate. The development of a single drug requires long research and development (R&D) processes that consist of clinical trials and large investment costs. Pharmaceutical firms have worked tirelessly to incorporate several methods and strategies that have raised the likelihood of success in their drug development initiatives (Henstock, 2020). One of the possible ways is to take advantage of the advances in big data and artificial intelligence (AI) that have experienced significant growth and development over recent years (Gupta et al., 2021).

Within the next few years, the drug discovery market is bound to grow tremendously and the value of AI in the drug discovery market is likely to rise at a compound annual growth rate of 40.8%. In 2019, the global value of AI in drug discovery was estimated at 260 million USD, and it is anticipated to reach 1.43 billion USD by 2024, according to a report by Markets and Markets (2019). Data mining, machine learning and artificial intelligence are some of the innovative technologies currently being exploited by the pharmaceutical industry to streamline drug research and development process. International pharmaceutical companies mainly drive this trend. (Jimenez-Luna et al., 2021; Réda et al., 2020).

In addition to the experimental process of drug discovery, AI technology must be strategically utilized in the process of business and management drug development planning. Pharmaceutical companies have to determine which drug/s they should give preference to when selecting their next development project taking into account organisational realities, reflective of both a managerial perspective and a business perspective. The drug development decision-making process often depends on qualitative evaluations determined by the perspectives of the company's board of directors and the technical competencies of the companies involved (Schuhmacher et al, 2021).

1.4 Research Gaps

Despite the growing interest in AI technologies within the pharmaceutical industry, there remains a significant research gap in understanding the extent to which these technologies enhance the speed, effectiveness, and success rates of drug development within R&D settings. Although many studies have expressed concerns about the potential of AI to transform drug discovery and development, there remains very little evidence about how it has practically changed the situation (Blanco-González et al., 2023; Serrano et al., 2024). Existing literature often focuses on theoretical frameworks and predictive models, but there is a lack of comprehensive studies that provide real-world data on AI's effectiveness in accelerating drug development processes (Blanco-González et al., 2023). Additionally, the role of research and development practices in adoption of AI in the pharmaceutical market is under-researched. Even though the role of the organizational culture and the dynamics of the market were explored in some studies, the role of R&D practices in AI adoption was not clearly identified (Serrano et al., 2024). Filling this gap is essential in establishing an adequate background of how AI can be practically applied in the pharmaceutical R&D to positively impact the outcomes of drug development. The purpose of this research is to reduce this gap by offering empirical information regarding practical usefulness of AI technologies in drug development, and assessing mediating role of R&D practices on AI implementation (Blanco-González et al., 2023; Serrano et al., 2024).

Although the level of the interest in the introduction of AI technologies into drug development is increasing, there is still a huge research gap on how to overcome the regulatory issues that come along with their implementation. The literature available reveals that AI has a possibility of transforming drug discovery and development by accelerating processes, improving accuracy, and reducing costs (McKinsey, 2024).

Nevertheless, the regulatory environment has not been able to keep up with the swift pace of developments in AI technology, leading to complexities and uncertainties in compliance (Sutherland, 2024). This gap is particularly evident in the pharmaceutical industry, where stringent regulatory norms are essential to ensure the safety, efficacy, and ethical use of AI-driven solutions (Fakhouri, 2024).

Additionally, although there is considerable evidence of the advantages of AI in drug development, little has been researched on the practical solutions to overcome the regulatory challenges (Haslam, 2024). Data privacy, algorithmic bias, accountability are also the ethical factors which further complicate the adoption process (Olabiyi, 2024). Such difficulties can only be addressed through in-depth knowledge of various regulatory systems and formulation of strong guidelines that can promote a balance between innovation and ethics. Therefore, this research aims to fill this gap by studying how to overcome the difficulties related to regulatory norms in the implementation of AI technologies in drug development. The hypothesis that standards, regulatory, and ethical considerations significantly influence AI adoption in the pharmaceutical industry underscores the need for targeted strategies to facilitate compliance and promote ethical AI practices.

The interest in incorporating the AI technologies in drug development is rising, yet there is a critical research gap in terms of how the organizational culture can support the effective integration of AI technologies in drug development. The existing literature underscores the transformative potential of AI in enhancing drug discovery processes, improving accuracy, and reducing costs (Murire, 2024). However, the impact of organizational agility and culture on AI adoption has not been extensively studied, particularly within the pharmaceutical industry (Goswami et al., 2023). The fact is that this gap is crucial because organizational culture is the key to shaping the attitude of employees towards new technologies and their readiness to accept changes. (Kriegel, 2025).

Additionally, although much evidence exists on the positive impact of AI on drug development, there is minimal research on how organizational culture can be utilised to counter the challenge of change resistance and create an amenable environment towards the seamless integration of AI (Pazhayattil & Konyu-Fogel, 2023). The ethical considerations, such as data privacy, algorithmic bias, and accountability, further complicate the adoption process (Murire, 2024).The analysis should begin with a thorough consideration of the cultural processes within pharmaceutical corporations and the creation of the strategies that would be used to ensure organizational culture supports AI implementation objectives. Thus, the proposed research will help to address this gap by offering new insights into how organizational culture of pharmaceutical companies may be streamlined to support successful AI integration in drug development. The hypothesis that organizational agility and culture significantly influence AI adoption in the pharmaceutical industry highlights the need for targeted strategies to foster a culture of innovation and agility, thereby facilitating successful AI integration.

Despite the increasing interest in the adoption of AI technologies in drug development, there remains a significant research gap in understanding the critical role of market dynamics in shaping pharmaceutical companies' readiness for successful AI integration. The existing literature highlights the transformative potential of AI in enhancing drug discovery processes, improving accuracy, and reducing costs (McKinsey, 2024). However, the impact of market landscape and dynamics on AI adoption has not been extensively studied, particularly within the pharmaceutical industry (Coherent Solutions, 2024). This gap is crucial as market dynamics, including competitive pressures, customer expectations, and regulatory changes, play a pivotal role in determining the readiness and capability of pharmaceutical companies to integrate AI into their operations (Quantzig, 2024).

In addition, though evidence on the usefulness of AI in drug development is abundant, little work has been done on how market dynamics can be utilized to address bottlenecks towards the adoption of AI and creating an environment conducive to the adoption of AI. (McKinsey, 2024). The ethical factors, including data privacy, algorithm bias, and accountability, make the adoption process more complicated as well (Coherent Solutions, 2024). To overcome these issues and address them, it is essential to have detailed knowledge about the market environment and develop strategies to align market dynamics with the objectives of the adoption of AI. Therefore, this research aims to fill this gap by investigating the critical, yet understudied, role of market dynamics in shaping pharmaceutical companies' readiness for successful AI integration in drug development. The hypothesis that market landscape and dynamics significantly influence AI adoption in the pharmaceutical industry underscores the need for targeted strategies to navigate market complexities and promote effective AI integration.

1.5 Research Problem

The introduction of artificial intelligence (AI) in the drug development process provides a great transformative opportunity to the pharmaceutical sector. However, this integration also brings a multitude of intricate challenges that need to be thoroughly investigated into Although artificial intelligence (AI) has been shown to offer a realistic, high-potential approach to increasing the pace of drug discovery, reducing cost considerably, and enhancing precision when it comes to drug candidate identification, there are still significant obstacles that hinder its widespread adoption.

The use of AI in analysing extensive biological data, such as proteomics and genomics could bring a great advantage in increasing the chances of success of the drug under review due to the streamlining of the research and development pipeline. Furthermore, the ethical consequences and ease of use of AI models, as well as the need for interdisciplinary collaborations along with robust validation procedures, are important aspects that need to be strategically prioritised in order to properly use AI's capacity to revolutionise pharmaceutical research.

This underscores the rationale of the study to examine how prioritised variables influence the adoption of Artificial intelligence in drug development in pharma industry. These variables include Research & Development, Std & Reg and Ethical Considerations, Organizational Agility and Culture, Market Landscape and Dynamics.

1.6 Purpose of Research

This underscores the rationale of the study to examine how prioritised variables influence the adoption of Artificial intelligence in drug development in pharma industry. This study will give relevant insights and recommendations to the industry stakeholders by undertaking an evaluation of current state, advantages, and disadvantages, regulatory and ethics aspect, organisational implications, key success factors, market dynamics, and general implications of drug development outcomes. The study findings will also offer considerable guidance to pharmaceutical companies in their strategic decision-making processes. The insights will assist companies to efficiently apply AI technologies to create innovation, enhance their efficiency, and eventually outcome improvement of patients.

1.7 Research Aims

The objective of this study is to explore the transformative nature of artificial intelligence (AI) in drug development within the pharmaceutical sector with a focus on how artificial intelligence (AI) can be used to enhance the productivity, accuracy and cost-effectiveness within the pharmaceutical industry.

This research aims at providing insight on the most appropriate way of applying AI in the pharmaceutical drug development in terms of both advantages and disadvantages and the challenges involved.

1.8 Research Questions

The following are the major proposed research questions and objectives to drug development in Pharma industry based on literature review.

Proposed Key Research Questions:

Q1: How does adoption of AI technologies in drug development influences the outcome of R&D Processes in pharmaceutical industry?

Q2: How do standards, regulations, and ethical considerations impact the adoption and implementation of AI technologies in drug development?

Q3: What role does organizational culture play in facilitating the integration of AI technologies in drug development within pharmaceutical companies?"

Q4: How does market dynamics influence the organizational readiness to effectively deploy AI technologies in drug development within pharmaceutical industry?

The research objectives are established in advance to clearly outline the intended outcomes of the study upon its completion. This study will attempt to answer the following key question and sub-questions presented below in order to achieve its objectives.

The focus of the study is on the following central question, and the sub-questions below, as means of achieving the stated objectives of the study.

To achieve the objectives of the study, the research seeks to answer the central question and its respective sub-questions identified below.

1.9 Structure of the Thesis

This thesis is divided into six (6) major chapters

Chapter 1 presented the research topic and offered a comprehensive overview of the study's history and background. It also addressed the significance of the study, outlined the research purpose, identified the research gap, and defined the research aim and questions.

Chapter 2 includes the literature review, illustrating the latest research on the topic. This review discusses the adoption of AI in the pharmaceutical the industry. The literature review enables the identification of gaps in existing research, elucidates the various variables influencing decisions about AI adoption in the pharmaceutical industry, formulates a conceptual model, and generates hypotheses.

Chapter 3 provides a comprehensive account of the study methodology used. This chapter offers a comprehensive description of the research study's methodology, approach, strategy, and philosophy. The discussion also covers population size and responder characteristics. The discussion comprises the design of the questionnaire, the hypotheses, and the methods used for data processing.

Chapter 4 comprises the data analysis, the results, and findings of the research study. It discusses the assessment of the measurement model concerning reliability and validity, indicator multicollinearity, and inter-construct correlation. The components of the structural model include correlation coefficients, an evaluation of each hypothesis, and the path coefficients for the drivers of each construct.

Chapter 5 provides an in-depth discussion of the research findings, examining how they align with the conceptual framework and existing literature. It highlights the connections between the study results and industry practices, showcasing practical implications. By correlating the research outcomes with theoretical perspectives and real-world applications, Chapter 5 offers a comprehensive understanding of the study's significance and impact.

Chapter 6 summarises the thesis with an analysis of the most important findings from the research. Several kinds of conclusions and recommendations is provided for the many stakeholders. This research has limitations, as do any empirically based theses. The limitations and prospective opportunities for future research in academia and industry are examined. The research reaffirms its significant academic contribution.

Appendices and references are provided at the end of this article to provide further information on its content.

1.10 Conclusion

The first section of this chapter delineates the pharmaceutical industry and artificial intelligence technology topics. The chapter provided a summary of the research and elucidated its significance for the pharmaceutical industry. The significance of the research, its objectives, aims, research purpose and research questions were elaborated extensively. Chapter 1 provided a comprehensive overview of the whole thesis.

Chapter 2 will discuss the literature about the dependent, independent, and sub-independent variables, as well as the outcomes and measures identified from the research gaps in the literature.

Chapter 2: Literature Review

2.1 Introduction

The introduction chapter delivered an exhaustive account of the research format by presenting background information alongside significance, research questions and objectives as well as data sources and respondent profiles and ethical issues alongside study limitations and an outline of each chapter. This section presented a brief analysis of different variables that influence the implementation of artificial intelligence in drug development practices within the Indian pharmaceutical industry.

The chapter presents a thorough discussion of literature review to identify existing gaps and propose research approaches that can benefit the pharmaceutical industry. The section starts with a fundamental introduction to Rogers' theory of diffusion of innovations. The literature review established four distinct variables including Research & Development and Standards & Regulations and Ethical Considerations alongside Organisational Agility and Culture and Market Landscape and Dynamics. The adoption of artificial intelligence in drug development within the pharmaceutical industry of India served as the study's dependent variable.

2.1.1 Importance of literature review

The literature review stands as an essential element that forms an integral part of any research project. This document unifies academic work on the subject matter by giving extensive details about the topic and showing the analysis and findings from existing literature. This defines the foundation upon which the current research can be conducted. Through this process researchers develop their research model and empirical testing hypotheses which establishes the direction for study analysis and investigation. The research will expand scientific knowledge by establishing unique findings and validating or rejecting existing research results.

The purpose of the literature review is to identify and analyse existing materials that provide support for the research topic under investigation. This chapter will analyse the identified gaps comprehensively and propose methods for the thesis to leverage them in establishing a distinctive commitment to the pharmaceutical industry for drug development. Several studies have been carried out within the pharmaceutical industry and documented in the literature. As a result, secondary data sources were used to determine what information was available on this topic within the scope of the present research.

The literature review conducted in this research provides an overview of the current state of knowledge pertaining to the topic being investigated. The establishment of knowledge boundaries enables the identification of gaps in current understanding. This study put forward by identifying the research gaps, which are the constraints of the research in the current literature, and the research results. The research gap serves as the basis for defining the research problem, justifying the proposed study, and contributing new insights to the existing body of knowledge.

2.1.2 Background of the literature review: Secondary sources of data

Multiple research papers have been published within the scientific literature about pharma and artificial intelligence. Secondary data sources provided the research basis to collect previous information about the Research topic. The assessment of existing literature for this review used leading international electronic databases that included EBSCOhost and ProQuest Central alongside Taylor & Francis Online and Google Scholar.

Research included thorough analysis of published articles from the mentioned academic journals: Future Journal of Pharmaceutical Sciences, International Journal of Advances in Computer Science and Technology, International Journal for Research in Applied Science and Engineering Technology, International Journal of Molecular Sciences, American Journal of Pharm tech Research, Intelligent Medicine, Expert Systems with Applications, and Emerging Trends of Artificial Intelligence.

A wide range of sources offered the data through scholarly journal articles available online alongside conference presentations and government reports and white papers from public and private organizations as well as pharmaceutical and artificial intelligence-related books and dissertations. This thesis considers research papers, publications and articles from the last five years. The main rationale for incorporating research literature or studies published prior to that date was that the research either represented a substantial contribution or the pivotal advancement in the field of pharma industry.

World-renowned authors who publish their work in peer-reviewed publications that focus on the pharmaceutical field provide essential quality for the literature. Literature depends on the closeness of article variables to thesis themes for determining usefulness. The analysis of current literature both presents recent publications and incorporates classic work from theory developers and model builders and other researchers who established early developments. All sections of the thesis need to meet these fundamental guidelines. The essential argument found within the thesis appears here.

2.2 The Pharma Industry

The fast progress of artificial intelligence techniques leads the worldwide pharmaceutical sector toward transformative changes in its operational paradigm. New technology advancements show the power to transform drug development methods through their ability to make faster more affordable drug production with better efficiency outcomes. Artificial intelligence (AI) has emerged as a blooming technology in several domains, and the pharmaceutical industry has begun noticing substantial advantages from its use. Artificial intelligence demonstrates substantial effectiveness throughout multiple sectors of the pharmaceutical industry such as drug research development and drugs repurposing as well as pharmaceutical productivity optimization and rapid clinical trial advancement. By minimising human labour and accelerating the achievement of goals, AI has proven to be a valuable tool in these fields (Vigneshwaran, 2022).

Additionally speeding up decision-making processes, which improves the production of high-quality products and maintains consistency across batches, artificial intelligence (AI) may significantly improve in the effective integration of the developed drug into the adequate dosage form and its optimisation. Clinical trials are crucial for verifying the safety and efficacy of a product, and the use of artificial intelligence (AI) may significantly enhance this process. Furthermore, artificial intelligence (AI) can contribute to market research and analysis, facilitating enhanced precision in product positioning and pricing strategies. Artificial intelligence (AI) is an integral component of the ongoing fourth industrial revolution. There are several initiatives underway to leverage artificial intelligence (AI) to transform current drug development methodologies.

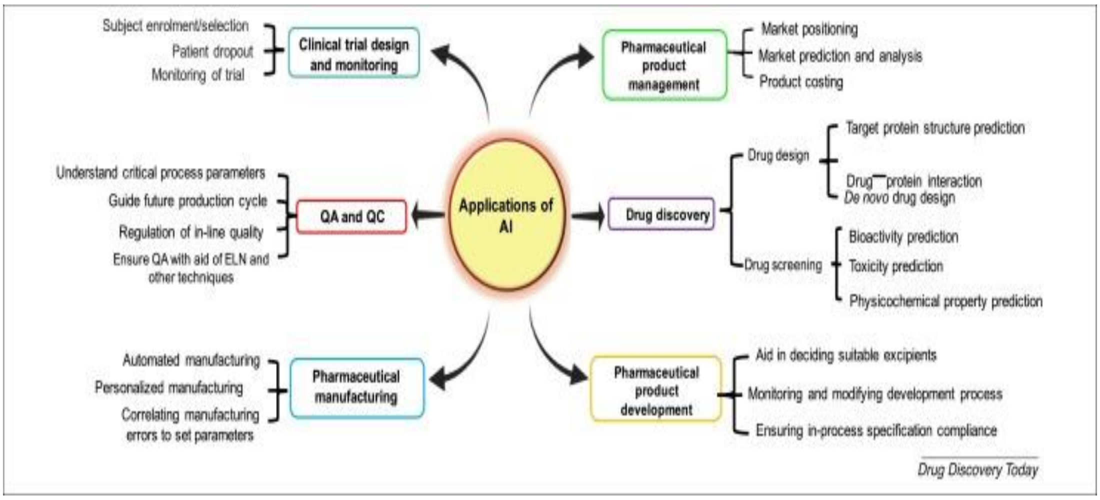
Within artificial intelligence (AI), machine learning (ML) is a discipline employing complex statistical methods and mathematical formulae to solve practical problems. Machine learning algorithms have increasingly gained recognition within the pharmaceutical industry, as they are employed in numerous supervised and unsupervised learning techniques throughout different stages of the drug development process (Lavanya et al., 2024).

The pharmaceutical industry is currently facing multiple challenges, including a decrease in new drug development, increased research and development costs, the impact of the ongoing economic recession, and more stringent regulatory requirements. Drugs develop through an extensive and expensive process spanning twelve years with an initial investment reaching 2.6 billion US dollars (Deng et al., 2021). Pharmaceutical companies currently confront substantial challenges because of high failure rates when seeking new drug approvals (Mak et al., 2019).There is a substantial need for the expedited development of new drugs to effectively treat various diseases. The demand for drug development in the pharmaceutical industry is under significant pressure. Drug development in the pharmaceutical sector experiences substantial market pressure due to rising demand. Research demonstrates that Artificial Intelligence and Machine Learning (AIML) presents a promising way for developing breakthroughs in these domains as well as meeting unmet customer requirements.

2.2.1 Artificial Intelligence (AI) in Pharma:

The innovation paradigm of the pharmaceutical industry has changed drastically because of AI-driven big data and analytics. Artificial intelligence has the capacity to enhance innovation, augment productivity, and provide better results throughout the value chain (Mishra, 2023). Artificial intelligence helps develop rational drug designs according to Duch (2007) while also supporting decisions about patient therapies which could include personalized pharmaceuticals and preserves clinical data for future pharmaceutical research (Curate, 2020). Artificial intelligence could assist in identifying the appropriate therapy for a patient.

Figure 3: Summarises the many uses of AI in the pharmaceutical industry (Curate, 2020)



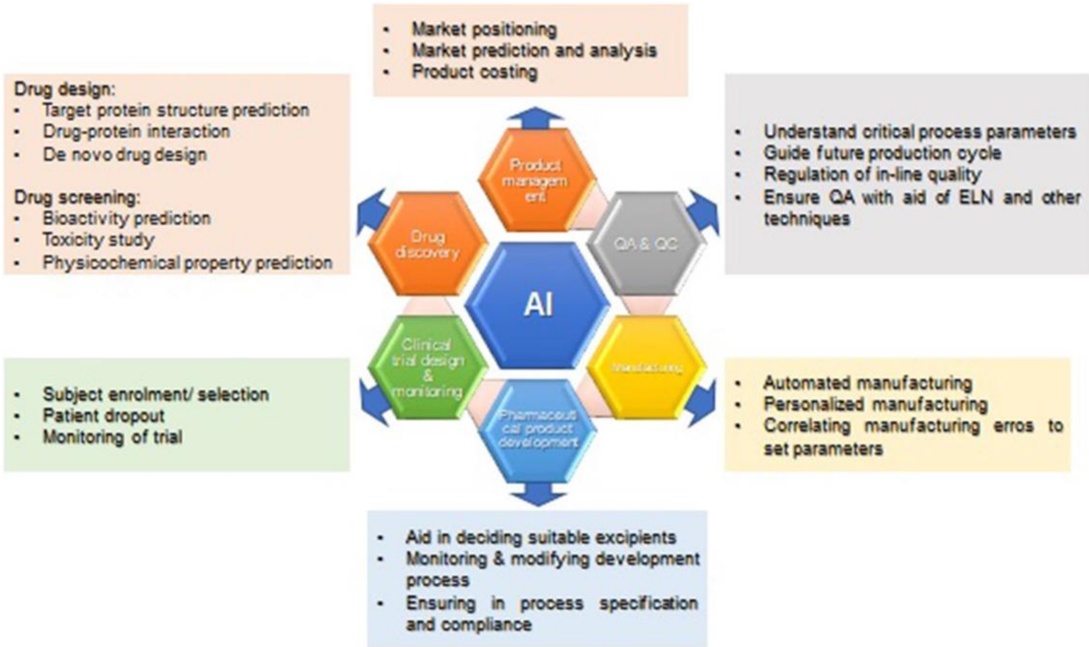
Artificial intelligence can perform tasks one thousand times more quickly, accurately and efficiently than humans can. Advancements in artificial intelligence have lightened the strain for humans (Chaudhari et al. 2020). Arvapalli (2020) explored how AI tools and manufacturing execution systems are used in pharmaceutical discovery along with automated control processes systems while reporting on AI predictions for new treatments as well as rare disease management and drug adherence and dosage issues.

Kulkov (2021) explored the role of artificial intelligence in business transformation with the study of fifteen pharmaceutical firms. The organisations of varying sizes use diverse approaches to transforming their critical and support business processes.

When it comes to R&D and the company's overall business processes, AI is getting the most attention at smaller businesses. Marketing, sales, and production are all areas where major corporations are undergoing transformation. In response, medium-sized companies must adapt their operations to compete in their respective fields of expertise.

The implementation of AI in drug development has significant potential to provide positive outcomes for developing novel therapies for untreatable diseases. Nonetheless, the need for the ongoing enhancement of AI systems is unequivocal (Sahoo & Dar, 2021). Enhancing AI involves the development of novel algorithms or the incorporation of diverse data sources into existing algorithms, with the latter posing more challenges due to legal and ethical constraints. Furthermore, inadequate data governance is a significant contributing reason to the failure of AI. A chemical database generated from traditional medicine will provide more data for innovative drug discovery; nevertheless, appropriate oversight is essential to assure the quality of the data produced. Consequently, pharmaceutical companies proficient in AI systems may play a pivotal role in developing these datasets and integrating them with their advanced AI-enhanced drug development platforms.

Figure 4: Applications of AI in various pharmaceutical business subfields (Paul et al., 2021)



Paul et al. (2021) studied the successful deployment of artificial intelligence (AI) throughout different pharmaceutical industry sectors in their recent study. Figure 4 illustrates how artificial intelligence finds applications across different segments of pharmaceutical business operations. The pharmaceutical industry utilizes crucial segments which comprise drug research development and drug repurposing along with pharmaceutical productivity enhancement as well as expediting the progress of clinical trials. The authors highlight the ability of AI to minimise human labour and expedite the achievement of goals within these domains. This paper examines the prospective role of artificial intelligence (AI) in the pharmaceutical industry, focusing on the tools and tactics used to implement AI. Additionally, it addresses the existing problems associated with AI adoption in this sector and proposes potential solutions to overcome them.

The pharmaceutical industry faces difficulties in maintaining its drug development initiatives owing to elevated research and development costs and reduced efficacy. This paper examines the main factors that contribute to attrition rates in the approval of new medications. It also discusses potential strategies and different types of AI-based software that can enhance the efficiency of the drug research process.

Additionally, it explores the collaboration between major players in the pharmaceutical industry and organizations specializing in AI-powered drug discovery (Sellwood et al., 2018).

AI-based techniques have recently presented a new target and its corresponding inhibitor, marking the first occurrence of such a discovery. In December 2020 in silico presented their small molecule inhibitor for investigational new drug (IND) enabling research and targeted early 2022 for clinical trials. If the trials are effective, it will be the first instance when an AI-based tool recommended a new target and its inhibitor and subsequently received approval.

Despite the presence of inevitable challenges and a significant workload required to integrate AI tools into the drug discovery cycle, it is certain that AI will undoubtedly bring about revolutionary transformations in the process of drug discovery and development in near future (Gupta et al., 2021).

2.2.2 AI in Drug Discovery and Development:

AI has established significant importance in drug research and development due to the growing number of AI and machine learning start-ups and pharmaceutical platform collaborations and the increasing number of research publications and reviews about applications, successes, and challenges (Liebman, 2022). Researchers and professionals are interested in AI as a pathway to pharma sector improvement. However, less study has been done on how AI could support pharma sector (Kulkov 2021).

Figure 5: AI in Drug Discovery (Kulkov 2021)

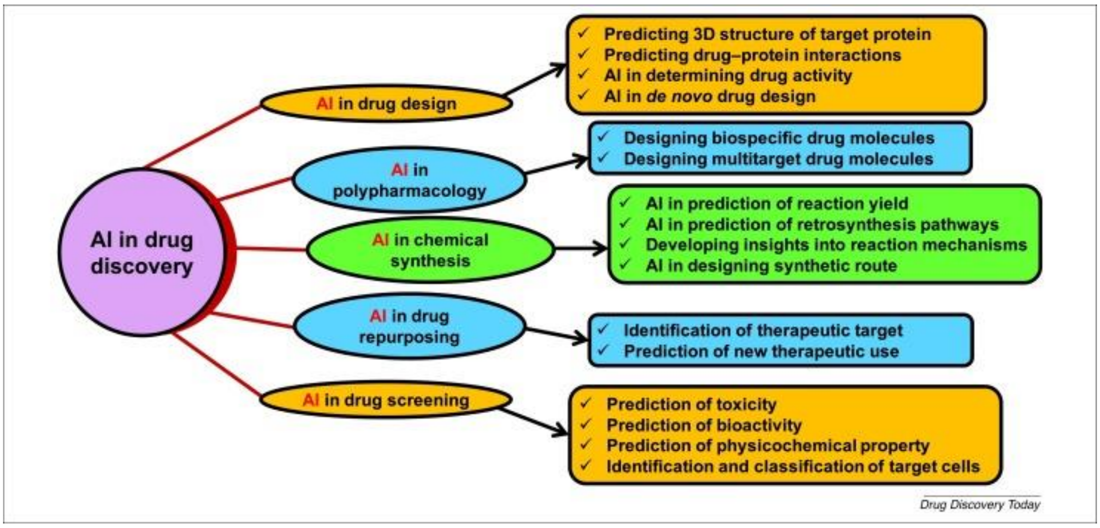


Figure 5 shows AI drug discovery applications. The huge chemical space of > 1060 compounds promote drug development (Mak & Pichika 2019). Lack of new technology makes medication research time-consuming and costly; AI may help. Artificial intelligence (AI) possesses capabilities for identifying hit and lead compounds together with target optimization and evaluation. (Mak & Pichika, 2019; Sellwood, 2018).

The drug development field may benefit from inputs such as clinical, electronic, and high-resolution imaging information. It is also possible to repurpose a drug molecule via the use of comprehensive target activity by expanding target profiles of pharmaceuticals to include additional targets with therapeutic potential (Quazi, 2021).

In drug discovery artificial intelligence performs three primary program phases. Phase-1 includes reviewing established literature alongside investigating how future drugs bind with their targets. The evaluation of therapeutic targets occurs during Phase-2 preclinical studies performed with animals. Artificial intelligence demonstrates the capability to improve trial operational efficiency and assist researchers in expediting the prediction of drug-animal model interactions. Following preclinical development and approval from the FDA, researchers conduct human trials during Phase 3. This is the most lengthy and costly phase of pharmaceutical production (Paul et al. 2021).

Drug development benefits from simple access to diverse experimental information including chemical information as well as transcriptomic and genomic data. Facing a large amount of biological data proves to be an overwhelming challenge when researchers try to convert it into meaningful computational models that fully understand disease development processes.

Advances in system biology and machine learning techniques presently pushes forward the development of efficient drugs. Drug development follows drug testing and drug repurposing among three essential automated procedures that link directly together. AI has brought transformative changes to pharmaceutical business operations at a substantial level. However, they remain underexplored. In the pharmaceutical sector, few effective AI applications exist (Hessler et al., 2018).

The potential of artificial intelligence techniques exists to transform decision-making strategies in healthcare through computational advancements at reduced costs though this requires perfect combinations between relevant questions and appropriate technologies. (Deng et al., 2021).

The field of drug development is being revolutionized by AI, as seen by the growing attention it is receiving from investors, scientists in industry and academia, and lawmakers. Effective drug development requires the optimisation of pharmacodynamic, pharmacokinetic, and clinical outcome characteristics. Hasselgren and Oprea, 2024, investigated the use of artificial intelligence in the three primary aspects of drug discovery: disease targets and therapeutic approaches, emphasising small molecule pharmaceuticals. Artificial intelligence techniques, such as generative chemistry, machine learning, and multi-property optimisation, have advanced several pharmaceuticals into clinical trials.

AI is used in the development of drugs to identify potential molecular structures and improve drug designs. AI assists in identifying existing drugs for potential therapeutic applications, minimising both money and time. AI improves quality control, simplifies operations, and optimises production parameters in manufacturing. Advanced process control and identification of errors help production, while AI-powered trend analysis helps identify and resolve possible issues. Clinical trials, which are vital to drug development, are improved by AI in patient recruiting, data processing, and monitoring. Machine learning algorithms can identify medical problems and forecast trial outcomes, improving patient therapy and trial success (Veeramani et al., 2023).

The pharmaceutical industry is using AI in drug development, employing it for tasks like as predicting molecular structures and improving drug designs. Moreover, AI facilitates the process of identifying existing drugs for novel therapeutic uses, hence reducing both time and financial costs. The use of artificial intelligence (AI) in manufacturing streamlines processes, enhances quality control, and optimizes production parameters. Efficient production is facilitated by advanced process control and fault detection, while the discovery and resolution of future issues are supported by AI-powered trend analysis. The use of AI in patient recruitment, data processing, and monitoring greatly enhances the effectiveness of clinical trials, which are a crucial phase in drug discovery. Utilizing AI algorithms to detect medical conditions and predict trial results has great potential for enhancing patient treatment and increasing the success rates of trials (Miller, 2021).

At this pivotal juncture, the pharmaceutical sector is embracing AI to abandon conventional drug discovery methods. Using AI to avoid pharmaceuticals with a lengthy development timeline and charging high fees to compensate for failed drugs might lead to more unique discoveries with shorter lead times (Archer & Germain, 2021).

AI in pharmaceutical research has great promise for personalized medicine and targeted therapeutics, especially when integrated with developing technologies such as genomics, proteomics, and metabolomics. Collaboration between academia, industry, and regulators is crucial for ethical AI use in medication research and development. Advanced AI research and training programs enable scientists and healthcare practitioners to maximize AI's potential, resulting in better patient outcomes and creative pharmaceutical therapies (Singh et al., 2023).

The authors presented an overview of the methods employed in the design of AI-based models for drug development. Their subsequent discussion focused on the application of AI methodologies in pharmaceutical research, specifically regarding toxicity, bioactivity, and the prediction of physicochemical properties. Additionally, they introduced AI-based models designed for the prediction of binding affinities, drug-target interactions, drug-target structures, and de novo drug design. The discussion highlighted the advancements in AI, particularly its capability to predict pharmacological synergism and antagonism, as well as its role in the development of nanomedicines. In conclusion ,they discussed the challenges and possible future directions of artificial intelligence in the field of drug development (Jain & Sharma, 2023).

The integration of AI with emerging technologies such as genomics, proteomics, and metabolomics presents significant potential for advancing pharmaceutical research. This integration offers the capability to deliver personalised treatment and targeted drugs. Collaboration among academic institutions, industry stakeholders, and regulatory agencies serves as crucial for the ethical incorporation of artificial intelligence in drug discovery and development processes. Continuous research and development in artificial intelligence (AI) methodologies, combined with comprehensive training initiatives, will empower scientists and healthcare practitioners to maximise the capabilities of AI. This will lead to enhanced patient outcomes and the development of innovative pharmaceutical therapies.

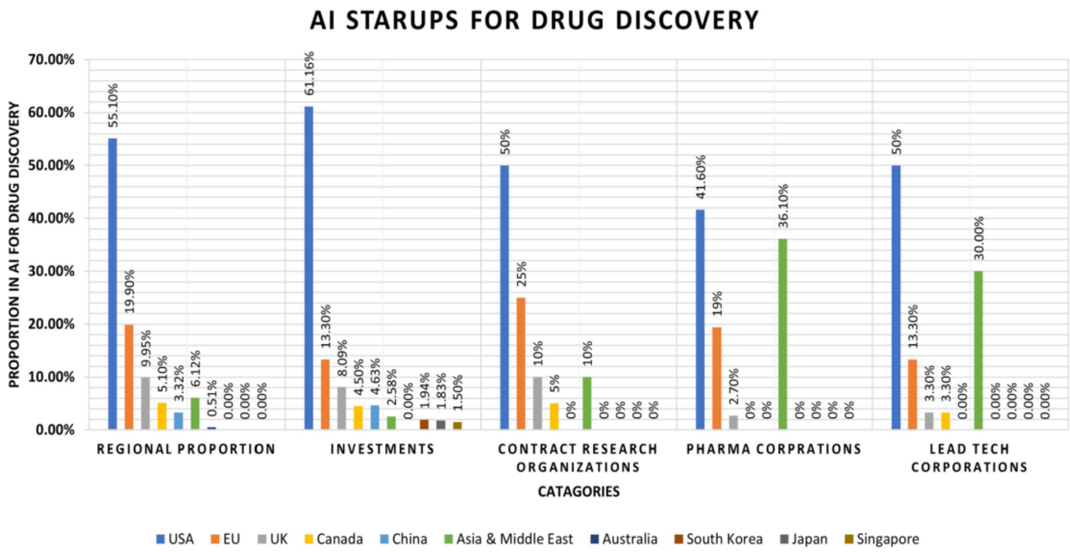
This integration has the potential to provide customized treatment and targeted drugs. Effective cooperation between academia, industry, and regulatory organizations is crucial for the ethical integration of artificial intelligence in the process of discovering and developing drugs. Continuous research and development in artificial intelligence (AI) approaches, together with thorough training programs, will enable scientists and healthcare professionals to fully use the potential of AI. This will result in improved patient outcomes and the creation of breakthrough pharmaceutical therapies.

The field of drug discovery significantly depends on artificial intelligence (AI) technology for its operations by assisting in the identification of new pharmacological compounds and appropriate patient populations, hence facilitating the development of more efficient and focused therapeutic interventions. Artificial intelligence (AI) also plays a significant role in several applications such as real-world data mining, therapeutic medication monitoring, and the optimization of clinical trial design and analysis. The use of artificial intelligence (AI) in various processes and the enhancement of decision-making capabilities have facilitated the advancement of customized treatment and enhanced operational efficiency within the pharmaceutical sector. The integration of artificial intelligence (AI) in the field of pharmacology is a noteworthy advancement with the objective of enhancing patient outcomes and propelling the progress of healthcare (Singh et al., 2023).

The United States is the leading entity in the implementation of artificial intelligence, hosting over fifty percent of the global AI companies focused on drug discovery. Statistics reveal that investor numbers have dramatically increased within the United States and European Union territories in the recent period. These regions together with the United Kingdom currently top the list of investors who support AI-driven drug discovery applications. Novartis functions as one of the leading pharmaceutical artificial intelligence companies throughout the United Kingdom and European Union. Both BenevolentAI and AstraZeneca which maintain their headquarters in the UK collaborate to use artificial intelligence for discovering new targets to treat chronic kidney disease.

China is currently prioritising investment in artificial intelligence for drug discovery, committing to an investment of US $5 billion in this sector. Tianjin, a major city in China, is set to allocate an investment of US $16 billion towards its AI sector, whereas Beijing plans to establish a $2.12 billion AI development initiative. By the year 2030, China aims to establish itself as the leader in the domain of AI-driven drug discovery start-ups (Qureshi et al., 2023). Figure 6 demonstrates the statistics of AI start-ups for drug discovery.

Figure 6: Statistics of AI start-ups for drug discovery (Qureshi et al., 2023)



2.2.3 AI in Drug Design

The first phase in drug development involves identifying the precise biological components that contribute to the spread of the disease. Many synthetic molecules are produced as potential drugs during development because they can interact with targets to achieve therapeutic effects. Quantitative structure-activity relationship (QSAR) or quantitative structure-property relationship (QSPR) analysis, together with computer-aided drug design, are used to determine pharmacokinetic and physicochemical properties. Predicting an NCE's lipophilicity and solubility uses deep learning and neural networks inspired by programmes like ADMET's predictor and ALGOPS (Bhattamisra et al., 2023). AI techniques contribute to enhancing clinical trial quality through complete process improvement of trial design along with patient selection and dosage selection and patient adherence and trial monitoring and endpoint analysis.

Selvaraj et al. (2022) addressed the role of AI and ML in aiding computer-assisted drug design, as well as the challenges and opportunities it presents to the pharma industry. Artificial Intelligence and Machine Learning technologies are used at any phase of computer-aided drug development, and their incorporation yields a high success rate of hit compounds. The integration of AI and ML with high-dimensional data has significantly progressed in its robust capabilities. Deploying AI/ML-integrated models for predicting clinical trial outcomes could reduce costs and enhance success rates.

Only one in ten drugs that make it through Phase I clinical testing really ends up helping people. We can't afford to depend on such a low, inefficient pace of production as our population grows older. By 2030, almost 1 in 8 people on Earth will be 65 or older, and "diseases of ageing" like Alzheimer's will create even more difficulties for society. However, we are on the cusp of a pharmacologically abundant planet. More than a hundred times cheaper, quicker, and more intelligently focused innovative drug development is on the horizon as artificial intelligence converges with vast datasets in everything from gene expression to blood testing (Sonawane et al, 2022).

By improving trial design (biomarkers, effectiveness metrics, dosage selection, trial length), target patient population selection, patient stratification, and assessment of patient samples, AI has great value in clinical testing, raising success rates. Evidence of AI's rising importance in the pharmaceutical industry may be seen in the proliferation of AI-focused start-ups and the increasing number of collaborations between pharmaceutical companies and AI platforms (Liebman, 2022).

Dudhe et al., (2021) showed that AI is capable of efficiently designing novel chemical structures, predicting for the required molecular property profiles, determining how to synthesis active chemicals, and identifying diseases and physical parameters for the purpose of medical treatment. With the use of AI, personalized/precision medicine might be the standard method for treating even the most common illnesses. AI has the capacity to correlate data in a way that is not generally feasible by humans, but physicians' intuition gives them an edge. When given enough relevant data, AI will be able to make diagnoses that human doctors would never consider. This would enable patients in the early phases of the disease's struggle (Arabi, 2017).

In recent years, the range of applications for artificial intelligence systems has significantly expanded to include de novo design and retrosynthetic analysis, indicating that we will see an increasing number of applications in fields with enormous datasets. With advancements in these several fields, we might envisage an increasing trend toward computer-automated drug discovery. Significant advances in robots will hasten this evolution (Hessler et al., 2018).

2.2.4 Machine Learning Approach:

Artificial Intelligence and Machine Learning technologies support the entire computer-aided drug development process, and their incorporation yields a high success rate of hit compounds. The integration of AI and ML with high-dimensional data has significantly progressed in its robust capabilities. Deploying AI/ML-integrated models for predicting clinical trial outcomes could reduce costs and enhance success rates. Machine learning technologies in various pharmaceutical sectors, such as drug design and discovery, pre formulation, and formulation demonstrated considerable opportunities for the development of applications that go beyond those of traditional machine learning (Damiati, 2020). In sectors like drug delivery, this practice has already started.

Deep learning, which is a category of AI, can help to discover and develop new drugs. Several machine learning methods have recently been developed or rediscovered (Yang et al., 2018). The use of AI and deep learning in this area is strengthened by historical evidence. Recently developed modelling algorithms also benefited greatly from unique data mining, curation, and management strategies. In conclusion, the progress made in AI and deep learning presents a great chance for the rational drug design and discovery process, which will influence humanity in the long run (Gupta et al., 2021). Machine learning and deep learning methods that support the pharmaceutical industry across the whole drug discovery process, from target validation through predictive biomarker development to clinical trials (Manne, 2021).

ML algorithms with DL techniques have made it possible to use AI in business and daily life. There are numerous opportunities for the use of AI tools, but there are also certain limitations and challenges, particularly if algorithms and models are intended to be employed in the mass production of drugs, either for pharmaceutical discovery or for monitoring the production process, or both. The challenges are due to the amount of data and the speed at which it is accumulating; dataset sizes; training/learning times; over or under-fitting of models, etc. (Djuris et al., 2021).

Multiple domains of drug development use artificial intelligence (AI) and machine learning (ML) applications to a greater extent. The size of data alongside Deep Neural Networks requires additional resources to manage the data and extend the software requirements stack as well as computational infrastructure. (Mishra & Muzumdar, 2021). Continuous model retraining and availability in production environments are becoming more and more important in the field of drug discovery (Spjuth et al., 2021). The prevalence and extensive use of machine learning in many industries have facilitated the development of adaptable tools and resources for researchers to develop diverse machine learning models. Talevi et al. (2020) summarised the uses of machine learning in drug discovery, drug development, and the post-approval period throughout.

Now, it is common practise to incorporate machine learning and deep learning algorithms into processes for developing therapeutic targets and discovering new drugs. Through high-throughput screening and high-throughput computer database analysis for lead and target identification technology, large data development has improved the reliability of applied machine learning and deep learning techniques. (Patel et al., 2020).

A fundamental prerequisite for integrating machine learning (ML) into drug discovery is the comprehensive traceability and repeatability of the model development and evaluation process. Consequently, researchers have developed a comprehensive, modular, and extendable software pipeline for constructing and disseminating machine learning models that predicts critical pharmaceutical parameters (Minnich et al., 2021). Considering emerging complex issues, such as developing algorithms that yield targeted recommendations for precision medicine and modelling drug therapy responses as results of a more extensive system than a limited number of genes, contemporary machine learning methodologies may serve as an invaluable tool in advancing drug development. One such example is building algorithms that provide focused suggestions for precision medicine (Réda et al., 2020).

The incorporation of artificial intelligence (AI) and machine learning (ML) into the drug discovery and development process has facilitated improved target precision, reduced toxicity, and enhanced dosage formulations (Jain, 2022). The different phases of drug development utilize artificial intelligence (AI) in widespread applications. The drug development process at different stages requires target identification then validation followed by hit detection and lead optimization steps. The drug screening method became more efficient through the implementation of AI technologies. The present review investigates how AI together with ML modelling influences typical drug discovery and development procedures. The analysis covers the different developmental phases that experienced transformative transformations through these technological developments (Dara et al., 2021).

Parvathaneni et al., (2023) explored AI and ML model adoption patterns that transform traditional pharmaceutical research through all phases of drug discovery .Due to the knowledge required to incorporate AI and ML into the drug research and development pipeline, partnerships between pharmaceutical enterprises and data science-based technology companies will continue to be necessary. Experts in the industry, such as Yann LeCun, CEO and President of IKTOS, have seen a rise in demand for completely in silico drug development.

The difficulties in utilising ML are mostly due to the inconsistent and unpredictable results produced by ML, which may restrict its use. In all sectors, rigorous and thorough high-dimensional data generation is still required. Vamathevan et al. (2019) explain that ML facilitates data-centric decision-making processes while simultaneously speeding up drug discovery through repeated problem-solving attempts that improve understanding of ML technique validation parameters. The present condition of machine learning and artificial intelligence approaches in computational drug development is demonstrated by Smith et al., (2018). The existing methodologies possess multiple domains for accelerating pharmaceutical research which challenge traditional industry norms.

AI acceptance in pharmaceutical discovery has improved to the point leading to better progress in medicinal chemistry. AI collaboration with advanced experimental techniques shows great promise to speed up the development of new enhanced drugs through efficient affordable attractive methodologies. DL-facilitated approaches have recently begun to address crucial challenges in the field of drug development. Several cutting-edge technical advancements, including "message-passing paradigms," "spatial-symmetry-preserving networks," "hybrid de novo design," and other innovative machine learning examples, will undoubtedly become widely used and greatly contribute to the analysis of numerous significant and fascinating inquiries (Ujjwal, 2024).

The use of AI in drug development will be significantly influenced by the allocation of open data and the augmentation of models. Artificial intelligence systems possess the ability to strengthen the determination of safety and effectiveness measurements for clinical trial agents. AI enables companies to reach optimal market alignment and pricing goals while performing complete market analysis and forecasting. Ath the present time there are no AI-enabled drugs accessible commercially however implementing this technology faces significant barriers. AI shows potential to develop into a vital industry tool for pharmaceuticals during the upcoming years. (Sarkar et al., 2023).

The use of data augmentation, explainable AI, and the integration of AI with conventional experimental approaches are emerging advancements in the field of artificial intelligence. These innovations have considerable potential in addressing the obstacles and constraints associated with AI in the realm of drug discovery. The increasing research focus and scrutiny from academics, pharmaceutical corporations, and regulatory agencies, coupled with the prospective advantages of artificial intelligence (AI), render it a captivating and optimistic field of research, holding the capacity to revolutionize the method of drug development.

Machine learning algorithms are able to recognize patterns and trends that may not be obvious to human researchers since they are based on the study of a substantial amount of data. This has the potential to make it possible to propose novel bioactive chemicals with minimal side effects considerably more quickly than is possible with traditional techniques (Gallego, 2021).

The detection of drug-drug interactions is another major use of artificial intelligence in the field of drug development. These interactions occur when multiple drugs are simultaneously administered to the same patient for the treatment of the same or distinct diseases, which may lead to changed effects or unpleasant responses. Approaches that are based on artificial intelligence may be used to identify this by evaluating big datasets of known drug interactions and finding patterns and trends (Blanco-González et al., 2023).

Chrobak (2023) findings also indicated that the use of artificial intelligence (AI) and machine learning (ML) techniques for the analysis of extensive datasets, the discovery of previously unidentified abaucin (*new antibiotics, such as abaucin)* targets, and the investigation of molecular interactions associated with known abaucins. A notable illustration of artificial intelligence's profound capacity in the field of drug development is the recent achievement in identifying Abaucin, an innovative pharmaceutical agent that has promise for addressing several medical conditions.

Problems with data quality, ethical quandaries, and potential biases are highlighted as roadblocks. Methods such as data augmentation and explainable AI are proposed as solutions to these problems. The importance of AI as a tool to augment human researchers' abilities rather than a replacement for their expertise is emphasized. Overcoming these challenges and capitalising on the power of AI may bring about a new era in the pharmaceutical industry's drug research and development processes (Mahato, 2023).

Through the integration of AI algorithms and bioinformatics knowledge, researchers are able to accelerate the process of discovering new drug targets, enhance the selection of potential drugs, and lay the foundation for customized healthcare that caters to the specific requirements of each patient. Using machine learning models, complicated information may be analyzed for accurate predictions and informed decision-making, expediting drug development. Convolutional neural networks (CNN) excel in image processing, biomarker discovery, and medicine formulation optimization. NLP enables scientific literature mining and analysis, providing significant insights and information.

Machine learning-based prediction models are becoming more important at the stage before preclinical research. This stage effectively minimizes costs and research durations in the process of discovering new drugs. This review article examines the application of new methodologies in recent research. An examination of the current advancements in this field will provide insights into the future development of cheminformatics in the near term. This analysis will encompass the limitations it poses as well as the notable achievements it has attained. This review will primarily concentrate on the methodologies employed for modelling molecular data, along with the biological issues tackled and the Machine Learning algorithms utilized in the field of drug discovery in recent times (Carracedo-reboredo et al., 2021).

The authors conducted a comprehensive analysis of recent applications of deep learning in the prediction of drug-target interactions (DTI) and the design of new drugs. Furthermore, we present an extensive overview of diverse drug and protein representations, deep learning (DL) models, as well as widely utilized benchmark datasets and tools for the purpose of model training and testing. In this section, we will discuss the remaining challenges that need to be addressed in order to fully realize the potential of DL-based DTI prediction and de novo drug design in the future (Kim et al., 2020).

As DL technology improves and drug-related data develops, DL-based techniques are being employed more and more throughout the drug development process. Consequently, they provide an SLR that incorporates the latest DL technologies and their uses in medication development, such as drug-target interactions (DTIs), drug-drug similarity interactions (DDIs), responsiveness and sensitivity to drugs, and prediction of drug side effects (Askr et al., 2023).

Researchers examine how artificial intelligence (AI) is used to anticipate pandemics, diagnose illnesses, develop medications, and give digital therapy and individualised treatment in their study. Deep learning and neural networks are popular AI tools; Bayesian nonparametric models are promising for clinical trial design; wearable devices and natural language processing are promising for patient identification and management (Bhattamisra et al., 2023).

2.2.5 Big Data:

The availability of massive datasets for potential drug candidates has ushered in the "big data era" in modern drug development study. The big data era's advances in AI have set the road for rational drug development and optimization in the future, which will benefit drug discovery and public health (Zhu, 2021). In the era of big data, traditional model analysis struggles to deal with the high dimensionality, complexity, and heterogeneity of large-scale modern biological data. As medical data continues to accumulate and AI algorithms become increasingly complex, it is expected that AI technology will eventually encompass every element of new drug discovery and development, consolidating it as a widespread approach for computer-aided drug design (Luo et al., 2018).

Advanced drug development platforms that incorporate big data via AI predictive models and autonomous synthesis are emerging, facilitated by the simultaneous advancement of automation and intelligent synthesis technologies. Wang et al. (2019) estimated that this will improve a situation currently characterised by lengthy drug development cycles, high costs, and a high failure rate.

The introduction of high-throughput screening methods in drug development and the computer revolution in the last century paved the way for the computational analysis and visualisation of bioactive compounds. This required molecular structures to be represented in a syntax that could be read by computers and understood by researchers from a wide range of disciplines. Due to the rapid advancement of computers and the difficulty of creating a representation that covers both structural and chemical features, a plethora of chemical representations have been produced over time. David, et al (2020) presented many of the electronic molecular and macromolecular representations utilised in drug discovery. This serve as a quick reference for structural representations that are crucial to the use of AI in the field of drug development.

Big data analytics and Industry/Pharma 4.0 principles need machine learning (ML) techniques like ANNs. The most frequent production methods have tested ANNs for numerous uses. ANNs might help create smart, autonomous pharmaceutical production lines. Automated systems may reduce human exposure to harmful procedures or drugs like hormones or cytostatics, speed up manufacturing, and reduce environmental burden (Nagy et al., 2022). AI's implementation in drug discovery, drug development, and healthcare poses many challenges. Effective regulation in this sector requires understanding the challenges of its use and deployment.

The future of drug development with AI technology is unquestionably bright. The major difference between these two realms is still a significant barrier. To create "drug discovery-specific" AI technology that really helps existing drug discovery, AI specialists and other domain experts will need to work closely together. Artificial intelligence analysts must comprehend the distinctive features of drug research data to develop relevant and comprehensible algorithms that elucidate modes of action and provide evidence for future decision-making. To advance AI systems, more domain experts will be needed to provide biological and chemical data with minimal errors in the experiments and to consolidate it on unified platforms.

The most crucial element, however, is for both sides to be open to cooperating and actively communicating in order to create a practical framework for a new revolution in drug development. This will offer a solid foundation for bridging this gap (Kim et al., 2020). AI has promise in many areas of the search for new drugs. The notion is not likely to solve every problem, but it might help scientists in their numerous roles and fields during the drug development research and delivery process, thus its use should be boosted. Domain-specific AI applications are only getting started in the business world. Drug discovery is still a plodding industry that relies on the careful management of risk and the creation of fresh research within the limits of responsibility to the patient and to shareholders, so we should not expect any sudden seismic shifts. Integrating both methods, however, has the potential to greatly boost productivity at some stages of the pipeline.

The development of artificial intelligence applications in pharmaceutical technology has increased throughout time by reducing expenses and time usage while increasing formula and process understanding. The pharmaceutical development process shows signs of improvement through AI technology, yet data management difficulties exist as a barrier because relevant information is lacking (Tripathi et al., 2021). Yang et. al (2019) analyzed how ML techniques function in virtual screening that uses structure and ligand information alongside de novo drug creation and pharmacological property estimation and drug repurposing and other additional areas. The authors summed up their study by discussing current method limitations with an eye towards future perspectives for AI-assisted drug discovery.

The author Arvapalli (2020) presented insights into drug discovery with AI tools and manufacturing execution systems as well as automated control processes and AI predictions of new treatments alongside novel peptides from natural foods and rare disease treatments including drug adherence and dosing and restrictions on AI implementation in pharma. The paper by Arabi (2021) outlines actual applications of AI and ML for treating difficult diseases including COVID-19, cancer and Alzheimer's disease. Ethical aspects along with projections about AI's future are included in the presented review. The research examines AI ethical aspects besides exploring forthcoming AI use cases.

2.3 Determinants of Adoption of AI:

A future in which artificial intelligence plays a transformational role in Pharma sector will be established through ongoing research, collaboration, and innovation within this sector.

The literature review identified the gaps in the current literature on the topic derived from secondary sources. Identifying the gaps facilitated the inference of the factors influencing the adoption of artificial intelligence in the pharmaceutical industry. The preliminary literature study indicates that the following independent factors influence the worldwide adoption of AI in the pharmaceutical industry. The literature supports the identification of these variables for the future study (research gap).

- Research and Development
- Standard, regulatory and ethics considerations
- Market landscape and dynamics
- Organizational agility and culture

The dependent variable is the adoption of AI in pharma industry. Benefits of AI was used as a measure of research outcomes.

2.3.1 Research & Development

The primary objective of Pharmaceutical Research and Development (R&D) is the discovery of new drugs and their subsequent introduction to the market. This process is characterised by its extensive duration and significant financial investment.

From initial therapeutic target selection through eventual human clinical trials, AI might be a helpful tool.AI and ML have become the cutting-edge technology projected to transform pharmaceutical R&D in the recent decade. The high expenditures of clinical trials also affect the therapeutic costs for patients. Pharmaceutical companies incorporate the R&D costs of unsuccessful trials into the pricing structure of approved drugs to maintain profitability (Bhattamisra et al., 2023).

Recent technological breakthroughs have removed hurdles to large-scale data collection and processing. Meanwhile, researching, manufacturing, and distributing new medications to patients has become more expensive. AI/ML techniques are appealing to the pharmaceutical industry due to their automation, predictive capabilities, and expected efficiency gains. Clinical trial preparation, execution, and analysis are the latest drug development phases to benefit from AI and ML. As AI/ML is being used in R&D, we must get through the buzzwords and noise (Kolluri et al., 2021).

Budget forecasts allow organizations to estimate their resource utilization across drug development phases for the accomplishment of strategic targets. During R&D development budgets assist managers to create and maintain financial control while developing a spending plan. Budgeting entails setting objectives, monitoring results, and assessing effectiveness for all pharmaceutical companies, regardless of size. This analysis assesses pharmaceutical R&D budgeting processes and makes suggestions to improve them so organisations may develop more effective budgets and budget reports (Ngoc & Oanh, 2019). To optimise the potential of the AI platform, it is essential to develop qualified data scientists and software engineers who possess a strong understanding of AI technology, as well as a clear awareness of the company's R&D goal and business objectives (Ganugu et al., 2023).

2.3.1.1 Data quality and quantity

AI methodologies enable the enhancement of medical data obtained from extensive molecular screening profiles in addition to individual health or pathology records and public health organisations. This application aims to accelerate processes and mitigate failures within the drug discovery pipeline (Tizhoosh et al., 2018; Qureshi et al., 2023).

A high-quality dataset is essential for the application of AI in drug discovery. The initial critical aspect is the accessibility of high-quality data suitable for training models based on AI techniques. The increasing volume of biological and chemical data is impeded by the challenge of inadequate data quality, which restricts the comprehensive utilisation of this information. Data curation can be implemented to systematically organise and manage raw data in order to address this issue. To achieve this objective, academic institutions and pharmaceutical companies must collaborate to establish data standards and frameworks that facilitate data collection and clearance (Aksu, 2013).

The quantity of data is a critical factor in the application of AI techniques. In practical scenarios, the quantity of positive samples is less than that of negative samples. The issue of sample imbalance will have a direct impact on the performance of the models. Therefore, it is recommended to employ oversampling and under sampling techniques to achieve balance in the datasets (Chen et al., 2023).

2.3.1.2 Technological advancement

The integration of artificial intelligence in pharmaceutical research and development is primarily influenced by various critical technological advancements. The advancements contribute to increased efficiency, enhanced accuracy, and greater personalisation in drug development processes, resulting in improved patient outcomes.

Ongoing research and development in artificial intelligence methodologies, along with extensive training initiatives, will enable scientists and healthcare practitioners to maximise the capabilities of AI. This advancement is anticipated to result in enhanced patient outcomes and the creation of novel pharmacological interventions (Singh et al., 2023).

The ability of AI to process large data collections enables it to find new drug candidates as well as predict molecule behaviour for faster drug development. Machine learning algorithms have the capability to enhance clinical trial designs through the prediction of patient responses and the identification of appropriate candidates, which in turn minimises the time and costs linked to trials (Daniel, 2024). AI enables the creation of personalised treatment plans through the analysis of individual genetic profiles and medical histories, thereby ensuring that therapies are specifically aligned with patient needs.

This method improves treatment effectiveness while reducing adverse effects, resulting in improved compliance among patients and outcomes. The integration of artificial intelligence and nanotechnology is transforming drug delivery systems, facilitating targeted therapies that enhance drug efficacy and safety (Daniel, 2024).

Artificial intelligence contributes to the design of these systems by forecasting drug interactions at the cellular level, thereby improving treatment precision. The advancements in the pharmaceutical industry offer substantial opportunities; however, challenges including regulatory hurdles and the necessity for strong data governance are critical factors that may influence the rapid pace of AI adoption within this sector.

2.3.1.3 Verification and Validation

The verification and validation processes for AI models in drug development encounter numerous substantial challenges that may impede their successful application within the pharmaceutical sector. The challenges arise from issues related to data quality, model interpretability, and the necessity for standardised validation protocols.

AI models frequently depend on datasets that can exhibit biases or inconsistencies, resulting in distorted outcomes and unreliable predictions. The intricate nature of biological data poses challenges for AI models, hindering the extraction of significant insights. The availability of limited data can constrain the training process of robust AI models, thereby affecting their generalisability (Ghislat et al., 2024). Numerous AI algorithms function as "black boxes," presenting difficulties for researchers in comprehending the decision-making processes, which is essential for obtaining regulatory approval (Kokudeva et al., 2024).

The impact of human bias in the processes of model development and evaluation may result in inaccuracies in assessing model performance (Ghislat et al., 2024). The lack of universally recognised standards for the verification and validation of in silico models presents challenges for the integration of AI in drug development (Musuamba et al., 2020). Effective validation necessitates collaboration among multiple stakeholders, a component that is frequently insufficient (Musuamba et al., 2020).

Despite these challenges, the potential of AI to transform drug development is substantial, requiring continuous efforts to tackle these issues and improve model reliability and acceptance in clinical environments.

2.3.1.4 Environmental Sustainability and Resilience

Numerous essential elements determine the integration of artificial intelligence within drug development procedures, such as the capabilities of data analysis, the efficiency of clinical trials, and the prospects for personalised medicine. Enhancing these factors can improve environmental resilience within pharmaceutical practices.

Artificial intelligence demonstrates proficiency in the analysis of extensive datasets, facilitating the identification of patterns that may be skipped by human researchers. This capability is essential for the process of drug discovery. Artificial neural networks (ANN) and genetic algorithms are frequently utilised to enhance drug formulations and anticipated interactions (Ali et al., 2024; Moingeon, 2021). Artificial intelligence optimises the design of clinical trials by pinpointing appropriate patient populations, leading to a decrease in both time and costs linked to drug development (Ali et al., 2024; Daniel, 2024).

The implementation of real-time monitoring for patients during clinical trials facilitates immediate adjustments, thereby enhancing outcomes and optimising resource utilisation (Ali et al., 2024). Artificial intelligence enables the creation of personalised treatments through the analysis of individual genetic profiles, resulting in more effective therapies that are tailored to the specific needs of patients (Daniel, 2024; Chinnaiyan et al., 2024). This method improves patient care while reducing waste in drug development processes, thereby supporting environmental sustainability (Moingeon, 2021). While AI offers various benefits, it is essential to address concerns related to ethical implications, regulatory challenges, and potential job displacement to ensure responsible implementation in drug development (Chinnaiyan et al., 2024).

2.3.1.5 Interpretability and Explainability

Several obstacles must be addressed to fully leverage AI in drug development. The requirements encompass the necessity for high-quality data, ensuring transparency and interpretability of AI models, addressing ethical considerations, and adhering to regulatory frameworks for the application of AI in drug development (Unogwu et al., 2023).

There are several significant obstacles in achieving interpretability and explainability in AI-driven drug development processes. The challenges arise from the intricate nature of AI models, the necessity for accessible explanations, and the incorporation of explainable AI (XAI) methodologies into current workflows. It is essential to address these issues to improve trust and efficacy in pharmaceutical applications. AI models, especially those utilising deep learning algorithms, frequently function as "black boxes," which complicates the comprehension of their decision-making processes (Jiménez-Luna et al., 2021).

Interpretable AI models are essential for building confidence and ensuring acceptability within the pharmaceutical sector. The models are utilised in the fields of pharmacokinetics and pharmacodynamics. The advancement of explainable artificial intelligence methodologies that provide clarity into the decision-making processes of AI models in pharmacokinetics and pharmacodynamics is likely to be the focus of research in the future. This will enable clinicians and researchers to understand and validate the predictions and recommendations generated by the model (Pawar, 2023).

2.3.2 Standard, Regulatory and Ethical Considerations

Pharmaceutical companies exhibit a high degree of dynamism. The recent updates to regulations by the FDA and EMA have increased the importance of regulatory compliance management for pharmaceutical manufacturers (Hagendorff, 2020). Pharmaceutical enterprises are required to adapt their compliance strategies in order to adhere to recently implemented regulations and anti-corruption laws. The United States Food and Drug Administration (FDA) governs regulatory measures on a global scale, mandating pharmaceutical and life sciences companies to proactively identify quality issues prior to impacting production processes.

The US FDA, MHRA, and other regulatory authorities' Standard Manufacturing Practise regulations have made the pharmaceutical industry firm, reactive, and delayed. The use of new technology in existing processes will improve agility, responsiveness to market changes (AmpleLogic, 2020). AI in manufacturing may boost quality control and reduce product recalls and remedial steps beyond the production. Artificial intelligence will transform pharmaceutical quality control in digital production facilities.

2.3.2.1 Intellectual property Protection

The standardisation and regulation of artificial intelligence (AI) within the pharmaceutical industry are essential for safeguarding intellectual property (IP) rights. As artificial intelligence technologies progress, they pose challenges to current intellectual property frameworks, requiring a unified regulatory strategy that harmonises innovation with legal protections. This document delineates the essential elements of how standardisation and regulation can improve intellectual property protection within the pharmaceutical industry. Various EU countries demonstrate distinct strategies regarding AI and intellectual property, with certain nations supporting legal reforms to acknowledge works generated by AI, whereas others depend on current frameworks (Sabet et al., 2024).

The patent system requires evolution to accommodate the role of AI in drug development, ensuring that inventions are evaluated equitably under existing laws, especially in relation to non-obviousness criteria (Fabris, 2020). The implementation of a standardised vocabulary for AI-related products has the potential to minimise confusion and improve compliance within the pharmaceutical sector (Higgins & Johner, 2023).

A cohesive strategy for validation processes in AI applications can enhance product development and facilitate regulatory approval, promoting innovation while safeguarding intellectual property rights (Higgins & Johner, 2023). Countries with advanced economies are implementing AI technologies to effectively monitor and enforce intellectual property rights, which can deter infringement and enhance protection (Sabet et al., 2024).

The swift advancement of AI technology may exceed the capacity of regulatory measures, resulting in potential weaknesses in intellectual property protection. This underscores the necessity for continuous communication among stakeholders to proactively adjust legal frameworks, ensuring that innovation is fostered while upholding strong intellectual property protections.

2.3.2.2 Ethical considerations

With the increasing integration of AI in medication research and clinical practice, it is essential to develop regulatory guidelines that ensure the safety, effectiveness, and ethical use of AI algorithms. These guidelines must also account for any ethical considerations that may emerge. Regulatory organisations are advised to establish guidelines that focus on data privacy, algorithm transparency, and validation criteria. This development should occur in close collaboration with researchers and industry partners (Pawar, 2023).

The integration of AI in pharmaceutical research and development necessitates meticulous attention to diverse standards and regulatory frameworks. As AI technologies advance, regulatory authorities are progressively responsible for ensuring that these advances conform to safety, effectiveness, and ethical standards. Regulatory organisations are formulating precise criteria to regulate the use of AI in clinical trials and drug development, ensuring that AI-driven procedures adhere to recognised safety and effectiveness requirements (Ibikunle et al., 2024). The integrity of data produced by AI systems is strongly emphasised. To ensure reliability of AI models, regulatory authorities must conduct rigorous assessment of them (Kokudeva et al., 2024).

The implementation of AI must prioritise patient safety, requiring comprehensive evaluations of AI-generated assessments in pharmaceutical development (Serrano et al., 2024). Ethical issues emerge with the interpretability of AI algorithms, underscoring the need for openness in AI decision-making processes (Kokudeva et al., 2024). Artificial Intelligence may enhance data gathering and processing, possibly resulting in expedited regulatory approvals for novel therapeutics (Ibikunle et al., 2024). AI may substantially decrease drug development costs by optimising trial designs and improving patient enrolment (Huanbutta et al., 2024).

The incorporation of AI offers several benefits, although it also poses issues including data protection, the need for sophisticated IT infrastructure, and the handling of unstructured data (Rakočević & Markovic, 2024). The pharmaceutical business prioritises the balance between innovation and regulatory compliance.

2.3.2.3 Data privacy and security

The integration of AI in pharmaceutical research is profoundly affected by data privacy and security regulations, which are essential for maintaining compliance and cultivating trust among stakeholders. As AI technologies progress, the need for stringent privacy protections is crucial to safeguard sensitive health data while facilitating innovation in drug research. Patients articulate apprehensions about data privacy, specifically about the ownership and security of their health information, which could hinder their willingness to give data for AI-driven drug development (Sabet et al., 2024).

Adherence to rules like GDPR and HIPAA is crucial for pharmaceutical firms, since non-compliance may result in legal consequences and loss of public trust (Arunachalam et al., 2024). Innovations such as the SecMPNN framework illustrate the secure implementation of AI, enabling efficient data processing while safeguarding privacy (Sabet et al., 2024). Effective communication among stakeholders is essential to tackle ethical and regulatory difficulties, guaranteeing that AI applications in drug development are both creative and compliant (Jena et al., 2024). The use of AI in drug development has significant promise, although the balance between innovation and rigorous data protection protocols constitutes a complex issue that must be addressed to get satisfactory outcomes.

2.3.2.4 Regulatory approvals and Risk Management

The incorporation of regulatory approvals plays a crucial role in the adoption of AI within drug development, highlighting both associated risks and potential benefits. Regulatory agencies are required to modify their frameworks to integrate AI technologies, while maintaining safety and efficacy standards in drug trials and marketing processes. Collaboration among stakeholders is required to enhance evaluation processes and standards. Agencies encounter challenges in evaluating AI models and data, potentially resulting in delays in the approval process (Oualikene-Gonin et al., 2024).

Regulatory measures can reduce risks and enhance fairness, guaranteeing the safety and efficacy of AI tools while building public trust (Pantanowitz et al., 2024). Rapid advancements in AI require flexible regulations to prevent hindering innovation in drug development. The complexity of AI introduces challenges related to accountability, ethical biases, and potential harm, thereby complicating regulatory oversight (Pantanowitz et al., 2024).

The unpredictable nature of AI risks poses challenges in establishing clear regulatory guidelines (Carpenter & Ezell, 2024). On the other hand, although regulatory challenges may hinder the adoption of AI, they also provide an essential framework to guarantee that innovations maintain patient safety and adhere to ethical standards. The integration of innovation and regulation presents a significant challenge within the dynamic environment of drug development.

2.3.2.5 Interoperability and Data standards

The integration of artificial intelligence in pharmaceutical drug development is significantly influenced by the principles of interoperability and established data standards. The implementation of these standards enables efficient data integration, improves the quality of AI applications, and expedites the drug discovery process.

Interoperability facilitates the harmonisation of diverse datasets, thereby enabling AI systems to efficiently analyse comprehensive information (Gawade et al., 2023).

The creation of Common Data Elements (CDEs) facilitates the standardisation of data formats, thereby improving the compatibility of datasets across various studies, as evidenced by a 32.4% mapping success rate in research (Long et al., 2024). Standardised terminologies, including the IDMP Ontology, enhance regulatory compliance and patient safety by promoting consistent data usage throughout the industry (Gawade et al., 2023). Establishing data standards is essential for preparing datasets for AI applications, thereby enhancing the accuracy and reliability of AI-driven insights in drug development (Chen et al., 2021).

While there are advantages, challenges persist, including the necessity for adaptable regulatory frameworks that can keep pace with swift AI developments while maintaining patient safety. Concerns regarding data privacy and the potential for job displacement resulting from automation continue to be prevalent (Daniel, 2024; Chinnaiyan et al., 2024).

2.3.3 Organizational Agility and Culture:

A literature study demonstrates that the pharmaceutical industry faces global employment issues. Despite decreased turnover, the pharmaceutical industry is more expensive. According to Nafisa (2017), research experts leaving companies impede product development and lose skills. Pharmaceutical representatives leave clients. Jindal, et al. (2016) found that productive employees had reduced attrition, higher productivity, and satisfied clients. Hussin et al. (2016) says pharmaceutical companies foster innovation by concentrating on employee satisfaction, working environment, organisational support, respect, and progress. Pharmaceutical professionals persevere for these and other reasons (Vijayakumar & John, 2018).

2.3.3.1 Vision & Mission

The effective implementation of AI in drug development and the pharmaceutical sector is determined by several critical factors, such as Vision and Mission, Organisational Agility, and Culture. The integration of AI technologies into company operations is significantly influenced by these elements, which ultimately impacts efficiency and innovation. A precise vision and mission enable pharmaceutical companies to align AI initiatives with their business goals. Novartis and AstraZeneca have effectively incorporated AI by concentrating on targeted goals, including the enhancement of drug discovery and the improvement of patient outcomes (Jain et al., 2024).

A clearly articulated mission enhances stakeholder commitment, enabling more seamless transitions to AI-driven processes. Organisational agility facilitates rapid adaptation to technological advancements and changes in the market. Agile organisations can implement AI solutions with greater efficiency, resulting in enhanced clinical trial success rates and reduced development costs (Rashid, 2021). The capacity to adapt and react to emerging data is important to maximising the predictive capabilities of AI in drug development (Erdogan et al., 2024).

An organisational culture that fosters innovation and collaboration is essential for the successful adoption of AI technologies. Organisations that promote for a data-driven approach facilitate the use of AI tools among employees, thereby improving productivity and decision-making (Singh et al., 2023).

Cultural resistance may impede the integration of AI, highlighting the necessity for leadership to cultivate an environment that supports change (Rakočević & Markovic, 2024). Conversely, although these factors are essential for the successful adoption of AI, challenges including data availability and ethical considerations may hinder progress. It is crucial to address these issues in order to fully comprehend the potential of AI within the pharmaceutical sector.

2.3.3.2 Leadership and Governance

Artificial intelligence technologies are being incorporated into several phases of the pharmaceutical lifecycle, ranging from drug research to post-market monitoring, presenting significant potential to redefine business models and operational procedures. These developments are bolstered by the cultivation of internal AI skills and strategic alliances with technology firms, which enable the incorporation of AI into practical operations.

The automation of production and quality control procedures with AI enhances efficiency and reduces human mistake (Rakočević & Markovic, 2024; Chhina et al., 2023).
Enhanced Decision-Making AI-driven data analysis yields insights that augment decision-making in governance and leadership, facilitating better informed and timely choices (Waza, 2024). The capacity of AI to handle and analyse extensive amounts of unstructured data is essential for personalised medicine and patient care, providing customised treatment choices based on individual medical information (Singh et al., 2023).The amalgamation of AI with electronic health records and cloud technology facilitates seamless data management and interoperability, essential for digital health projects (Harrer et al., 2024).

Pharmaceutical businesses are investing in artificial intelligence skills and establishing collaborations with technology firms to use advanced analytics and machine learning for competitive advantage (Henstock, 2020; Harrer et al., 2024). The commitment of senior executives in leading pharmaceutical businesses highlights the strategic significance of AI in facilitating digital transformation (Henstock, 2020). Although AI provides considerable advantages, its implementation in the pharmaceutical sector also poses hurdles, including the need for sophisticated IT infrastructure and proficient individuals to handle AI systems efficiently. Moreover, issues regarding data security and possible biases in AI algorithms must be resolved to guarantee the ethical and fair use of AI technology (Chhina et al., 2023).

2.3.3.3 Talent Management

The incorporation of talent management in the pharmaceutical sector markedly improves organisational agility, especially in the context of implementing AI for drug development. Effective talent management practices enhance agile competencies in employees, allowing organisations to quickly adjust to the rapid changes brought about by AI technologies. This synergy is essential for effectively managing the complex aspects of drug development processes, which are being transformed by AI.

Talent management emphasises the enhancement of skills that correspond with AI technologies, including data analysis and machine learning, which are critical for drug discovery and development. Employees who are actively engaged demonstrate a higher propensity to adopt AI tools, which facilitates enhanced collaboration and fosters innovation within the realm of drug development (Nigam & Chavla, 2022). Organisations that emphasise continuous training in AI applications are positioned to more effectively address market demands and technological advancements (Rakočević & Markovic, 2024).

Artificial intelligence minimises the duration and expenses linked to drug development, optimising processes that historically required years (Chinnaiyan et al., 2024). The analysis of extensive datasets is facilitated by AI, which improves the precision of identifying drug candidates and predicting safety (Daniel, 2024). Artificial intelligence enables the development of customised therapies, consistent with the industry's transition to precision medicine (Chinnaiyan et al., 2024). The integration of AI and talent management offers various benefits; however, it also introduces concerns regarding job displacement and necessitates a flexible regulatory framework to maintain a balance between patient safety and innovation (Chinnaiyan et al., 2024; Daniel, 2024).

2.3.3.4 Collaboration

To construct comprehensive and diverse datasets, collaboration among researchers, pharmaceutical companies, and regulatory agencies is essential. The establishment of collaborative networks and data-sharing initiatives will facilitate the development of robust artificial intelligence models, thereby enhancing their applicability in the fields of pharmacokinetics and pharmacodynamics (Pawar, 2023). It is essential to foster a culture among stakeholders that encourages the adoption of computational models and the application of their results. Healthcare data science needs maximum potential realization with combined efforts between industry, academia and stakeholders and through educational programs that train medical and computer science professionals.

Enabling collaboration between researchers, clinicians, engineers, and data scientists is crucial for the advancement of AI-driven drug delivery systems. This interdisciplinary approach combines subject expertise, technological proficiency, and clinical understanding to promote innovation and address challenges successfully (Ali, 2023). Researchers and health care professionals provide specific expertise in administering the drug, pharmacology, and patient care, promoting the advancement of AI-driven systems and ensuring that AI algorithms conform to therapeutic standards.

Data scientists together with engineers offer specific knowledge in artificial intelligence, machine learning, data analysis as well as algorithm development. This collaboration facilitates the optimisation of AI-driven drug delivery systems. The exchange of knowledge occurs through joint research activities together with interdisciplinary workshops and research centers for experts. The programs help to facilitate both the exchange of technological knowledge and funding schemes for AI-based drug delivery studies among multiple research disciplines. Providing cross-disciplinary education lets professionals develop shared skills and perspectives that boost communication and teamwork skills necessary for effective collaborative effort (Vidhya et al., 2023).

There is a need for an increased number of workshops focused on AI applications in drug discovery and computational biology at leading AI conferences such as NeuralIPS and ICML The long-term objectives of AI drug discovery will benefit from establishing educational programs that focus on this specific field. The pharmaceutical company AstraZeneca collaborated with Dialogue for Reverse Engineering Assessments and Methods (DREAM) through their drug-combination challenge that combined information from 11,576 experiments spanning 910 drug pairs tested on 85 molecularly characterized cancer cell lines according to Qureshi et al (2023).

2.3.3.5 Change management

Implementing AI in the pharmaceutical industry presents a complex array of challenges that span technological, economic, and organizational domains. These challenges are compounded by the sensitive nature of the industry, which deals with critical data and requires stringent regulatory compliance. The transition to AI-driven processes necessitates a comprehensive change management strategy to address these multifaceted issues effectively.

Building AI infrastructure is costly and complex, especially for small and medium-sized enterprises (SMEs). Integrating AI into existing legacy systems is time-consuming and requires continuous updates due to the dynamic nature of AI technologies (Rane et al., 2024). The pharmaceutical industry handles sensitive data, making data privacy and security a significant concern. AI systems must be designed to protect this data while complying with regulatory standards (Rane et al., 2024).

AI's "black box" nature can make its decision-making processes opaque, posing challenges in understanding and trust, which are crucial in a highly regulated industry like pharmaceuticals (Engel et al., 2021). There is a global scarcity of technically skilled professionals in AI, data science, and machine learning, which is a barrier to effective AI implementation (Rane et al., 2024). Employees need to be trained to adapt to AI tools, which requires significant investment in skill development and change management strategies that emphasize communication and phased implementation (DiMasi, 2015). Implementing AI requires establishing ethical frameworks to ensure that AI systems do not perpetuate biases or unethical practices (DiMasi, 2015). The pharmaceutical industry is heavily regulated, and AI systems must comply with varying legal standards across regions, which can complicate implementation (Rane et al., 2024).

Effective change management is crucial for AI integration. This includes fostering a culture of innovation, developing cross-functional teams, and ensuring alignment with organizational goals (Valtiner & Reidl, 2021; Ademola, 2024). There may be resistance from employees who fear job displacement or are skeptical of AI's benefits. Addressing these concerns through transparent communication and involving employees in the change process is essential (Shafiabady et al., 2023).

While AI offers transformative potential for the pharmaceutical industry, these challenges highlight the need for a strategic approach to change management. Organizations must balance technological advancements with ethical, regulatory, and human considerations to successfully integrate AI into their operations.

2.3.4 Market Landscape and Dynamics

Pharmaceutical businesses use artificial intelligence technologies to decrease operational costs along with minimizing operational failure risks. Since 2015 AI marketplaces have achieved $200 million revenue growth up to $700 million in 2018 and experts predict a $5 billion revenue level by 2024 (Chen et al., 2021). Numerous pharmaceutical companies have invested in AI technologies and are actively pursuing further investments. They have collaborated with an artificial intelligence organisation to establish essential healthcare tools. Consequently, significant global collaborations between the pharmaceutical sector and the artificial intelligence industry have been developed.

It is possible that artificial intelligence may revolutionise the process of drug discovery by significantly lowering the amount of time required for research and development (R&D), cutting the expenses associated with the creation of drugs, and accelerating the approval process. Organisations must allocate resources towards AI solutions that are in alignment with their business objectives. It is essential to ensure ethical practices are upheld and to foster continuous innovation in order to sustain a competitive advantage within the dynamic market environment (Fahim et al., 2024). By 2029, it is anticipated that the Asia-Pacific artificial intelligence in drug discovery market industry will account for USD 3,424.04 MN. Studies on repurposing existing drugs might also stand to profit from the use of AI technology (Data Bridge Market Research, 2022).

2.3.4.1 Cost & Investments

The integration of Artificial Intelligence (AI) and Machine Learning (ML) into drug development is radically changing the pharmaceutical industry as costs decrease, timelines are shortened, and results are more precise in drug discovery efforts. AI technology providers such as natural language processing and machine learning are used to streamline various stages of drug development that include target identification, clinical trials, and optimal costs, and drug development duration. This transition is propelled by substantial investments and partnerships between artificial intelligence companies and pharmaceutical organisations, with the objective of enhancing drug approval rates and minimising clinical trial failures.

The conventional drug development process incurs significant costs, averaging approximately $2.6 billion, and typically requires more than ten years to reach completion (Linton-Reid, 2020). Artificial intelligence possesses the capability to substantially decrease these expenses through the optimisation of research and development processes, thereby alleviating the financial burden on pharmaceutical companies (Ghule, 2024). Investments in AI-driven drug discovery are on the rise, evidenced by multiple partnerships between AI companies and leading pharmaceutical firms, including the collaboration between Numerate and Takeda Pharmaceutical (Smalley, 2017).

A significant alteration in the pharmaceutical industry is observed as more artificial intelligence technologies are being incorporated into the drug discovery and development process (Rashid, 2021). AI companies emerging are also becoming important players in terms of introducing tools that enhance efficiency and effectiveness of the drug development processes (Nagra et al., 2023). The market is increasingly competitive, as AI-driven solutions provide a strategic advantage by decreasing time-to-market and enhancing drug efficacy (Schulz et al., 2015). AI and ML are being increasingly applied in various stages of a drug development process, which include drug target identification, drug repurposing, and biomarker discovery (Ghule, 2024).

Personalised medicine is experiencing advancements due to AI, with algorithms processing patient-specific data to customise treatments, thereby improving patient outcomes (Ghule, 2024). AI and ML present significant advancements in drug development; however, challenges persist, including the requirement for extensive datasets to train algorithms and the integration of AI within current regulatory frameworks. The variation in AI adoption among various regions and organisations presents a challenge to its broad implementation (Belsare & Burušić, 2023). The continuous investments and partnerships demonstrate an increasing acknowledgement of the potential for AI to transform the pharmaceutical sector.

2.3.4.2 Patient centricity and personalization

Implementation of the artificial intelligence (AI) and the machine learning (ML) advancements in drug development is transforming the pharmaceutical field with its focus on patient-centered approach and personalisation. Drug discovery, production, and supply chain management are augmented using AI and machine learning technology to create a more efficient and personalised healthcare solution. Patient-centricity emerged as an important development in the pharmaceutical industry, as the issue of patient interaction with the drug development process is becoming of paramount interest. The concomitant focus on AI/ML and care-centricity is changing the marketplace and shaping adoption strategies in the pharmaceutical industry.

Artificial intelligence enhances the drug discovery process through the analysis of extensive datasets, enabling the prediction of viable drug candidates and the repurposing of current medications. This approach effectively minimises the time and financial resources required for drug development (Pranay et al., 2023; Belsare & Burušić, 2023). Machine learning models leverage real-world data to enhance patient outcomes, facilitate disease management, and optimise treatment regimens (Zou & Li, 2022). AI technologies improve manufacturing processes by ensuring quality, reducing waste, and optimising production, which results in much faster market delivery of pharmaceuticals (Belsare & Burušić, 2023).

Pharmaceutical companies are increasingly adopting patient-centric initiatives, including patient advisory boards and lay-language clinical trial summaries, to engage patients in the drug development process (Lamberti & Awatin, 2017). Personalized medicine, supported by pharmacogenomics, customises drug therapies to align with individual patient profiles, thereby improving treatment efficacy and patient satisfaction (Moumtzoglou, 2024).

Digital health technologies (DHTs) enable the remote and continuous collection of patient data, yielding insights that align drug development processes with patient needs and regulatory standards (Aryal et al., 2024). The pharmaceutical industry is experiencing a transition from a focus on products to an emphasis on patients, motivated by the necessity for significant patient involvement and improved research methodologies (Getz, 2015). Despite the potential of AI and machine learning, challenges including data governance, system interoperability, and evolving regulatory frameworks impede widespread adoption (Zou & Li, 2022; Mishra et al., 2023).

The implementation of patient-centric strategies differs among organisations, shaped by elements such as management support, available resources, and levels of investment (Lamberti & Awatin, 2017). AI/ML and patient-centricity present significant advancements in drug development; however, there are concerns regarding the pharmaceutical industry's genuine dedication to these initiatives. Critics contend that patient-centricity can occasionally be apparent, prioritising commercial interests over genuine improvements in patient outcomes (Arnold & Kerridge, 2023). The integration of AI/ML in healthcare must address challenges associated with data privacy and regulatory compliance to fully realise its potential (Zou & Li, 2022).

2.3.4.3 Market size and growth potential

The potential for growth in the AI-driven drug development market is influenced by several critical factors, such as its capacity to enhance operational efficiency, lower costs, and increase precision in the processes of drug discovery and development. Artificial intelligence technologies are revolutionising traditional methods through the acceleration of extensive data analysis, enhancement of clinical trial processes, and support for personalised medicine approaches. The innovations are making the process of drug development shorter and more probabilistic of successful drug approvals. Due to unmet medical needs, which affect the large number of patients worldwide, there is the continuous introduction to the market of new drug molecules which potentially treat specific diseases. Throughout the years, numerous groundbreaking pharmaceuticals have been identified and approved by the FDA (Shareef et al., 2024).

AI also can be used to analyse big biological and chemical data to accurately predict which molecules may be a potential drug candidate, massively speeding up preliminary drug development (Chinnaiyan et al., 2024; Ghule, 2024). The use of machine learning models allows predicting the efficacy and safety of compounds to avoid conducting large-scale animal testing and prioritise and maximise the post-identification of lead compounds (Ghule, 2024; Narayan et al., 2024). Machine learning-enabled in silico trials and virtual screening tools streamline drug development by modelling interactions at the biological level and in clinical trial settings, thus minimising the costs and time to take a pharmaceutical to market (Ibikunle et al., 2024; Nailwal et al., 2024).

Artificial intelligence reduces the costs of the development process due to the improvement of research and development processes that consist of drug target identification, lead optimisation, and clinical trial design (Ghule, 2024; Narayan et al., 2024). Data collection and analysis can easily be automated using AI and can be more efficient when doing clinical trials. This advance will lead to a much faster and cheaper process using patient recruitment and real-time optimisation of trial designs, leading to faster drug development (Narayan et al., 2024; Nailwal et al., 2024).

Artificial intelligence can promote personalised treatment plans based on the individualised data about patients, which makes the treatment plans more potent and they are likely to adhere to treatment better (Ghule, 2024; Afrose et al., 2024). Artificial intelligence comes in handy in tailoring treatment procedures and medication doses to the uniqueness of the patient thus, maximising treatment success and reducing side effects (Narayan et al., 2024; Vidhya et al., 2023). AI can strengthen the regulatory procedures, providing significant evidence to inform regulatory decisions, which leads to the shortening of the time to regulatory approval of a new drug (Ibikunle et al., 2024; Unogwu et al., 2023).

Regardless of these developments, issues such as data security, interpretability and the ethical aspect remains a problem to truly capitalise on AI in drug development (Nailwal et al., 2024; Unogwu et al., 2023). AI has significant potential in terms of progress in the sphere of drug development; nevertheless, it is important to consider existing obstacles concerning its realization. These include the guarantee of the quality of data, the clarity of the models and solving the ethical and regulatory concerns. The resolve of these dilemmas is necessary to achieve sustainable implementation of AI in pharmaceutical development, so the results will become more equitable.

2.3.4.4 Market disruption and business model innovation

The integration of AI within the pharmaceutical sector is being fuelled by multiple critical elements that markedly impact the innovation of business models. The factors encompass improved efficiency in drug discovery, capacity for managing extensive datasets, and the incorporation of AI into clinical trials and personalised medicine. AI technologies enhance the efficiency of the drug discovery process by minimising the time and costs involved in identifying new drug targets and optimising compounds (Rakočević & Markovic, 2024; Dave, 2024). With high-throughput screening and predictive modelling, lead molecules are identified at a faster pace, and thus the chances of late-stage failures are minimised (Oza et al., 2023).

Artificial intelligence enhances the analysis of large datasets, thereby optimising decision-making processes in drug development and therapeutic monitoring (Dave, 2024; Patel, 2024). The integration of artificial intelligence with cloud technology facilitates enhanced data sharing and collaboration among pharmaceutical companies (Harrer et al., 2024).

Artificial intelligence improves the design and implementation of clinical trials, resulting in enhanced patient monitoring and tailored treatment strategies (Harrer et al., 2024; Patel, 2024). The implementation of artificial intelligence in digital health applications, including telehealth and digital therapeutics, creates new market opportunities and business models for pharmaceutical companies (Harrer et al., 2024).

On the other hand, although AI offers various benefits, obstacles such as ethical issues related to data privacy and the requirement for qualified personnel might prevent its extensive implementation in the pharmaceutical industry.

2.3.4.5 Market perception and Stigma

The integration of artificial intelligence in drug development processes within the pharmaceutical sector is notably affected by market perceptions and associated stigma. AI offers significant transformative potential; however, concerns related to its implementation could hinder progress. The perception of AI as an advanced tool is compared with concerns regarding job displacement and regulatory challenges, resulting in reluctance towards its adoption (Chinnaiyan et al., 2024; Fahim et al., 2024). The absence of confidence in the decision-making capabilities of AI may hinder stakeholders from fully leveraging its potential, thereby affecting investment and collaboration opportunities (Fahim et al., 2024).

Stigmas associated with privacy, data security, and the ethical implications of AI in healthcare may pose obstacles to acceptance (Fahim et al., 2024; Daniel, 2024). Conventional methodologies in drug development can impede the integration of AI technologies, as stakeholders often favour established practices over novel strategies

(Rakočević & Markovic, 2024; Erdogan et al., 2024). With the evidence supporting the efficacy of AI in drug discovery and development, the perceptions about AI are likely to change to a more positive attitude, and acceptance and penetration into the industry will be more acceptable. Such a move can boost efficiency in the provision of patient care and operational efficiency.

2.4 Outcome and measures:

In this research, outcomes denote the precise results or effects that a suggested framework seeks to attain, illustrating the influence of independent factors on dependent variables. Measures are the established criteria used to assess these results, guaranteeing their validity and reliability in representing the efficacy of the study of hypothesis.

2.4.1 Knowledge creation

Knowledge creation as an important result indicator of assessing the effectiveness of research and development (R&D), especially the process of integrating artificial intelligence (AI) in the development of drugs in the pharmaceutical industry. Artificial intelligence improves the drug discovery process through accelerated hypothesis testing, optimised data analysis, and innovative insights into molecular interactions. Artificial intelligence tools, including deep learning and generative algorithms, facilitate the acceleration of molecular simulations and drug repurposing, while also improving the exploitation and generation of knowledge (Conde-Torres et al., 2023). Additionally, the integration of AI into current research and development workflows enables researchers to detect distinct patterns within datasets, which is essential for innovative drug design and minimising clinical failures (Lee, 2023).

The utilisation of AI-driven knowledge creation is demonstrated through its capacity to handle extensive unstructured data and derive actionable insights. IBM’s Deep Search and AI-powered Bayesian optimisation techniques enable researchers to efficiently navigate extensive repositories of scientific literature and data, facilitating hypothesis validation and molecule simulation (Lee, 2023). The implementation of these innovations leads to a substantial reduction in both costs and time, concurrently enhancing the precision of drug discovery initiatives. Furthermore, the collaborative function of AI alongside conventional R&D methodologies establishes a balance between innovation and empirical validation, promoting sustainable growth in pharmaceutical advancements (Conde-Torres et al., 2023).

The potential of AI to transform knowledge creation demonstrates its significance in enhancing pharmaceutical research and development, indicating a fundamental change in the conceptualisation and development of new therapeutic agents.

2.4.2 Compliance and resilience

Resilience and compliance are an essential part of non-AI-driven drug development. It is also an important result in terms of the introduction of artificial intelligence (AI) in the field of drug development, particularly in such a strictly regulated industry as pharmaceuticals. Compliance guarantees alignment with changing regulatory frameworks, whereas resilience enables organisations to adjust to challenges, including evolving global standards or ethical issues. AI technologies, such as Natural Language Processing (NLP), are essential in regulatory compliance by optimising processes including regulatory intelligence, data standardisation, and risk management. NLP facilitates the conversion of unstructured text found in regulatory documents into structured data suitable for analysis. This process enables organisations to effectively align information with standards such as the Identification of Medicinal Products (IDMP) (Pharmaphorum, 2023).

Additionally, the incorporation of AI into risk management strategies allows pharmaceutical companies to proactively identify and mitigate risks throughout the drug development process and in post-market phases. Through the analysis of internal data, such as corrective actions, alongside external insights, including FDA guidelines, AI facilitates real-time decision-making and promotes sustainable compliance practices. Regulatory bodies like the FDA and EMA are advancing the idea of a risk-based approach to accommodate the use of AI where transparency of predictions and safety outcomes of AI systems are prioritised (Crisafulli et al., 2024).

Building compliance and resilience through AI aligns with regulatory expectations and fosters a competitive advantage by enabling faster, safer, and ethically sound drug development processes. The dual focus enhances the sustainable integration of AI within the pharmaceutical sector.

2.4.3 Organisational adaptivity

Organisational adaptivity will make a critical measure outcome of the independent variable, Organisational Agility and Culture because it concerns the adoption of artificial intelligence (AI) in the process of drug development in the pharmaceutical industry. Adaptivity denotes the capacity of the organisation to respond efficiently to technological disruptions, regulatory modifications, and competitive pressures resulting from the integration of AI. AI is driving significant transformations in drug discovery processes, including accelerated compound screening, predictive modelling, and the development of personalised medicine. Consequently, pharmaceutical companies are required to adjust their strategies, workflows, and talent development initiatives to maintain competitiveness (Conde-Torres et al., 2023; Chokshi et al., 2023).

Adaptivity involves changing organisational structures to improve cross-functional partnership and integration of AI into the research and development, and data-driven decision-making to streamline drug development. It necessitates the upskilling of employees to effectively connect AI tools with conventional pharmaceutical knowledge. The effectiveness of these modifications is contingent upon the integration of a culture that promotes continuous learning and innovation within the organisation (Halmaghi & Todarita, 2023).

Adaptive organisations exhibit resilience by effectively managing risks, including data privacy issues, ethical challenges, and the potential for biases in AI algorithms. Their goals are aligned with stakeholder expectations, ensuring the ethical and compliant utilisation of AI while leveraging it to achieve a competitive advantage

(Blanco-González et al., 2023). Organisations that do not adjust may encounter diminished operational efficiency and face the risk of lagging in the swiftly changing pharmaceutical environment.

2.4.4 Business Growth

Business growth serves as a critical outcome measure in the analysis of market dynamics within the context of AI-driven drug development.

The expansion of a company is one of the key result indicators, which depends on the industry changes associated with the adoption of artificial intelligence (AI) in drug development procedures in the field of pharmaceuticals. AI technologies have revolutionized the drug discovery and development across drug research, shortening research paths, reducing the costs of this process and increasing competitiveness in the market. AI-driven platforms, such as those utilised by Exscientia and Recursion, have shown the capability to create new molecules and progress them to clinical trials significantly faster than conventional methods. This advancement improves organisational agility and facilitates quicker market entry (Coherent Solutions, 2024).

The pharmaceutical market powered by AI is undergoing significant expansion, with forecasts indicating a rise in market value from $1.8 billion in 2023 to more than $13 billion by 2034, propelled by innovations in drug discovery platforms and clinical research technologies. Reported growth can be explained by the ability of AI to streamline the processes, advance data-guided decision making, and expand the range of possibilities in precision medicine, including complex diseases like cancer and Alzheimer's (Doherty et al., 2023).

Additionally, the implementation of AI-driven optimisations in supply chain and manufacturing processes plays a crucial role in enhancing business growth through waste reduction, efficiency improvement, and timely product delivery. The advancements are in alignment with the strategic objectives of pharmaceutical companies, aiming for scalability and sustainability while effectively addressing global healthcare challenges (Coherent Solutions, 2024).

The incorporation of artificial intelligence in drug development provides a competitive edge by facilitating innovation, enhancing patient outcomes, and generating prospects for sustained business growth within the evolving pharmaceutical sector.

2.5 AI Implementation and Challenges

It has been predicted that in the near future, AI technology will include several facets of modern drug discovery and development. This expansion will be facilitated by the accumulation of a greater volume of medical data and the refinement of more efficient AI algorithms. Consequently, AI is poised to become a prevalent method in computer-aided drug design. According to the study conducted by Bender and Cortes-Cirian in 2021, The field of drug development is now in its nascent phase of incorporating novel and developing experimental and computational tools (Manne & Kantheti, 2021).

The potential transformation of the process will likely happen because to significant advancements in computational capabilities, along with breakthroughs in artificial intelligence (AI) technology. Pharmaceutical industry is currently faced with the difficulties of sustaining its drug development programmes with the rising costs of R&D and waning efficiency. One important consideration is on the decision making process of how to proceed in relying on these technologies to improve on the existing pipeline and processes, or consider the potential of a re-engineering process given these technologies (Bender & Cortes-Cirian, 2021).

In a recent publication, Oprea (2020) provided a discussion about the challenges and developments in the area of artificial intelligence and machine learning (AI/ML) linked to target identification. The author also explored the use of AI/ML in generative chemistry for the purpose of small molecule drug development. Additionally, Oprea (2020) considered the possible influence of AI/ML on the evaluation of clinical trial results. The integration of human cognitive abilities with artificial intelligence (AI) systems is anticipated to occur within the next decade. Artificial intelligence (AI) has promise in mitigating the exorbitant computational expenses associated with doing virtual screening on very large chemical libraries. This approach also aims to highlight the main constraints of the AL method.

The iterative characteristic of the AL algorithm makes it unsuitable in the complex model development and ensemble-based epistemic uncertainty quantification approaches, thus, placing constraints on its utilization. The resolution of these challenges has significant importance in the advancement of artificial intelligence, necessitating the collective participation and endeavours of scholars across several disciplines (Yu, J., Li, X., & Zheng, M., 2021). Artificial intelligence (AI) has the capacity to greatly improve the quality of healthcare provided for specialised medical fields and uncommon medical conditions. According to Ahuja (2019), optimal patient care in the future may be achieved by the allocation of resources towards acquiring a comprehensive understanding of the underlying principles that propel artificial intelligence (AI) technology.

Deng, J. et al. (2022) concluded in their review that the use of AI in the drug development process presents both significant prospects and significant obstacles. To make successful applications, it is necessary to understand these fundamental concepts and assess the objective, the data, the representation of the molecules, the architecting of the model, and the general learning paradigm. Having the complete knowledge in these parts, the next relevant contributions can be made to change this sphere greatly. The paper by Qureshi et al., (2023) addresses the developments of artificial intelligence in the field of drug discovery application as well as the problems appearing in its aspect, namely, the representation and learning of data, and the current level of hype, hope and reality associated with the given topic. Five different elements serve as barriers to artificial intelligence implementation within the pharmaceutical industry. The pharmaceutical industry faces implementation delays from five main barriers which include insufficient strategies along with skills shortages and departmental barriers and minimal managerial engagement and employee resistance to adopting new behaviors. Machine learning and AI projects in pharmaceutical research experience delays due to these factors present in the pharmaceutical sector. This investigation addresses an important gap in pharmaceutical production sector understanding about implementing AI and ML technologies. Quantitative findings enable leaders to outline the strategic implementation strategy for new technologies throughout their field. (Pazhayattil & Konyu-Fogel, 2023)

AI is more than just a theoretical possibility; it is now here, changing rapidly, and will become a real tool that is crucial to the ongoing pursuits of precision medicine and drug development.

By expediting the early-stage identification of candidate compounds with the best chance of effectively influencing the targeted ailment, AI approaches may speed up the drug development process as a whole and the optimization or targeting of molecules in particular. In instance, by analysing historical data, deep learning algorithms may predict how various bodily systems and tissues would react to a certain medication. In addition, AI can help with patient stratification during clinical trial preparation or treatment optimization utilising patients' reactions and individual characteristics to select target groups for clinical trials and to forecast disease development via molecular data derived from tissue samples (Deng et al., 2022).

A very large percentage of conventional drug design researchers still view AI-enabled drug design as mostly incremental and still predominantly hype-driven. The steps towards the development of a drug are the de novo design of the drug, the drug response analysis, the optimisation of the molecule, and the screening. However, a substantial percentage of drug candidates fail during clinical trials, resulting in incremental advancements in the field.

Coupled with the complexity of the biological space, chemical space and clinical space, the concurrent optimisation of all the three spaces is a challenging task (Qureshi et al., 2023). In the drug discovery processes, quality/safety is the primary consideration in preference over speed and cost. Developing an AI system capable of achieving multi-objective optimisation within a complex, multi-dimensional space presents a significant challenge. This endeavour requires collaborative efforts across various disciplines in both academia and industry.

Because of its implementation, ML has the potential to increase the speed of the process, decrease the rate of failure and increase data-driven decision making in the drug discovery and development processes. However, in order to encourage future investment from large pharmaceutical and technology businesses, ML applications will need to be effective in the clinical context .Increasing understanding of the aspects that are required to validate ML techniques is essential (Vamathevan et al., 2019).

Acceptance of AI drug discovery will improve due to the growing popularity of explainable AI, which has three main techniques, namely: feature attribution, instance-based molecular counterfactual explanation and uncertainty estimation. AI is not perfect yet, and there are data black holes, that is why combining human and machine intelligence is a successful tactic. The next few years will have general high-level research and deployment software packages with straightforward documentation that make access to these methods easily available (Kalayil et al., 2022).

It is highly probable that AI will yield transformative advancements in the drug research and development process in the near future, notwithstanding the inevitable challenges and the considerable effort required to integrate AI technologies into the drug discovery cycle.

Despite its significance, the role that AI plays in causing shifts in pharmaceutical industry workflows has not been well explored. However, there is a lack of effective AI implementations in the pharmaceutical sector. Some of the initiatives that have been completed successfully in specific areas and are not widely publicised.

The benefits of artificial intelligence technology will outweigh their downsides when those benefits have fully developed. As a result, AI-enabled methodologies will pave the way for advancements in a wide range of fields related to healthcare and pharmaceuticals, which might be pivotal for future studies.

There are five reasons that may give rise to delays in the deployment of artificial Intelligence in the pharmaceutical industry. Some of these factors are absence of strategy, inability to attract talent, silos, lack of executive support and reluctance to change their behaviour. These can lead to the slowed down projects of machine learning and AI in the pharmaceutical industry. The study closes knowledge gap related to pharmaceutical production industry on using the ML and AI. The quantitative data can now be used by the leaders in the field to develop a strategy of implementing the new technologies (Pazhayattil & Konyu-Fogel, 2023).

We argue that AI is more than just a theoretical possibility; it is now here, changing rapidly, and will become a real tool that is crucial to the ongoing pursuits of precision medicine and drug development.

By accelerating the preliminary screening of candidate drugs with the highest probability of successfully impacting the targeted condition, AI applications can both accelerate the drug development process overall and streamline the process of optimization or targeting of a given molecule. In instance, by analysing historical data, deep learning algorithms may predict how various bodily systems and tissues would react to a certain medication. AI supports patient stratification for clinical trials as well as treatment optimization through individual patient characteristics and response data during trial planning. The system also helps find specialized patient groups through biological sample analyses to forecast disease changes. (Deng et al., 2022).

2.6 Rogers' theory of diffusion of innovations

The theory of diffusion of innovations is attributed to be popularised by Everett Rogers (2003). The theory attempts to describe how, why and at what pace innovations and technology diffusion take place. The theory classifies adopters of new ideas and technology under the innovators, early adopters, and early majority, late majority and laggards.

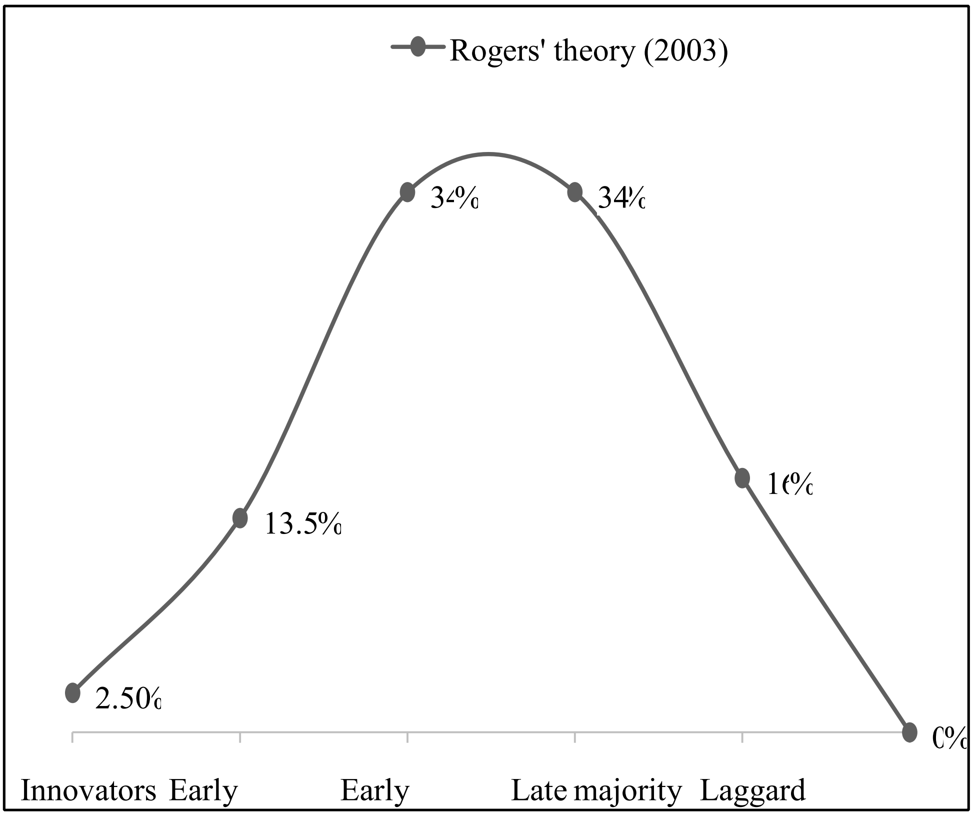
Rogers diffusion of innovations theory has been deemed too suitable in examining the process of absorption of technology in institutions of higher learning and learning facilities (Sahin, 2006). Since most diffusion studies deal with technological innovations, Rogers (2003) tended to use the term technology and innovation interchangeably.

The normal distribution graph of Rogers is illustrated in tabular form as table 1, below.

Table 1: Adopter categorisation on the basis of innovativeness

Category	Percentage
Innovators	2.5%
Early adopters	13.5%
Early majority	34%
Late majority	34%
Laggards	16%

Figure 7: Everett Rogers' diffusion of innovations model



(Source: Diffusion of Innovations, fifth edition by Everett M. Rogers)

The theory of diffusion of innovations presented by Rogers became the starting point in formulating the research survey instrument due to the inclusion of a factor that measures the rate at which individuals adopt a new technology. An additional category of adopters named “never adopt” appeared within the study. The analysis in Chapter 5 evaluates how the collected survey results match the conclusions derived from Rogers’ diffusion of innovations model.

2.7 Conclusion

The review is a synthesis of research done on the same written in secondary books and published on the internet. It establishes research gaps, lays out the position of the thesis, builds a model within the context of existing gaps. In this research, there were four independent variables, and one dependent variable. The independent variables are Research & Development Standards and Regulations, Ethical Considerations, Organisational Agility and Culture and Market Landscape and Dynamics. Artificial intelligence adoption has been used as the dependent variable, which was measured based on the research findings. This chapter also elaborates on Rogers' theory.

This chapter entails a thorough description of research methodology while justifying all methods used throughout the thesis. The chapter details data collection methods while presenting survey equipment design alongside pilot study and main study features. This section presents information about sample collection while exploring the respondent profile along with their associated demographic characteristics among other aspects.

Chapter 3: Research Methodology

3.1 Introduction

The given chapter provides the systematic explication of the methodology of the literature-review. The study provided a summary of significant online literature pertinent to the research studies. The review identified deficiencies in existing research, which facilitated the development of a foundation for hypothesis formulation and the creation of the research model. The study indicates that four separate factors influence the incorporation of AI into drug development processes. The thesis used Rogers' theory of the spread of innovations in its approach.

The identified research challenges form the theoretical context of the present study. Through this, research aims and hypotheses arising in the study are based. The section presents detailed information about the research methods which were utilized throughout the study. The section covers available data sources together with ethical issues in data collection and details the survey instrument's design procedure. The text describes the survey participants as well as their general profile and outlines their distribution by gender, age, employment status, and location. The document provides information about pilot and main study design features alongside the statistical methods needed to generate meaningful results. The document describes how this study developed hypotheses through systematic procedures starting from research problems and objectives.

3.2 Research Objectives

The research goals outlined for this study seek to address identified deficiencies and solve main issues that emerged from this study while establishing an extensive framework to understand AI adoption factors in pharmaceutical drug development.

O1: to investigate the degree to which AI technologies improve the speed, effectiveness, and success rates of drug development within R and D settings.

O2: to study how to overcome the difficulties related to regulatory norms in implementation of AI technologies in drug development.

O3: to provide new insights for organisational culture within Pharmaceutical companies for effective implementation of AI in drug development

O4: to investigate the critical, yet understudied, role of market dynamics in shaping pharmaceutical companies' readiness for successful AI integration in drug development.

3.3 Research hypotheses

The study hypotheses eventually emerged from the research objective which itself derived from both research gaps and research problem alongside the question for the study. Table 2 shows the theoretical steps in the process and the development of hypotheses in this research.

Table 2: Methodological development of the hypotheses

Sr. No.	Research Hypotheses
H1	Research and development significantly influence AI adoption in drug development in pharma industry.
H2	Standards, regulatory and ethical considerations significantly influence AI adoption in drug development in pharma industry.
H3	Organizational Agility and Culture significantly influences AI adoption in drug development in pharma industry.
H4	Market Landscape and Dynamics significantly influences AI adoption in drug development in pharma industry.

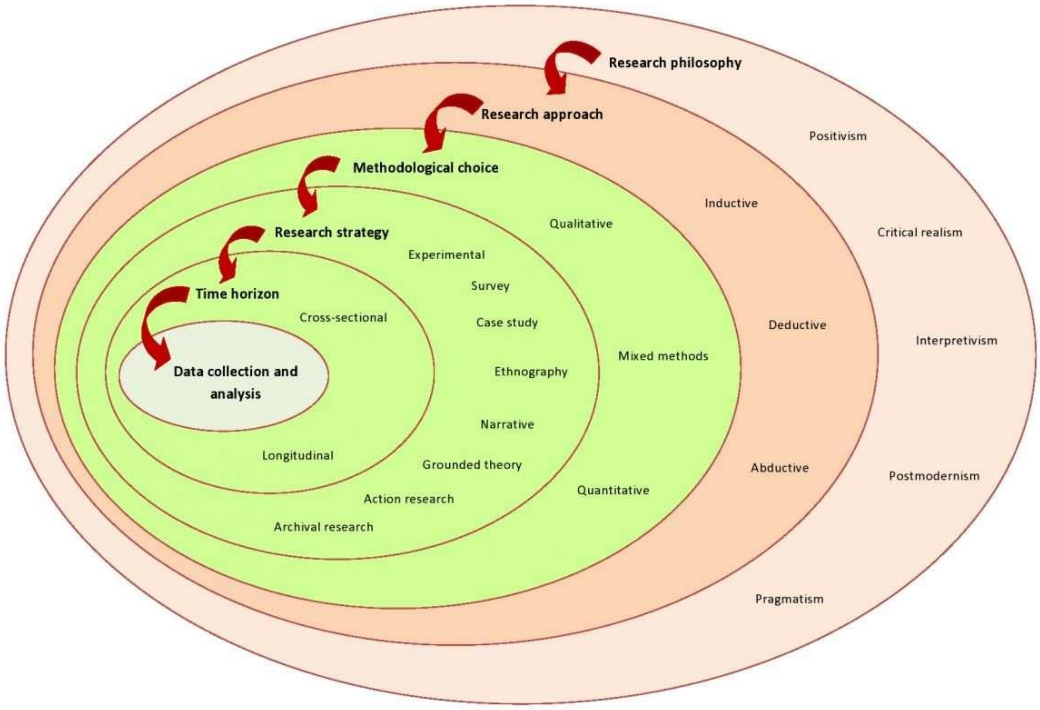
3.4 Research design

Research design establishes research features from numerous available options to the researcher and explains why researchers select specific attributes.

3.4.1 Research design and methodology

This thesis contains a methodological research strategy which was the main element. In this research, the used approach was that of hypothetico-deductive with research philosophy being positivism. In this study, reductionist methodology was used and this involves breaking down complex qualities into simple sets of variables to establish the likelihood of finding cause and effect. This study used a cross-sectional design by gathering data from entirely distinct groups post-data collection. A positive approach to research became dominant at this time. While conducting this study the researcher worked to preserve neutrality during analysis of each observation. The research thesis organized its contents into various sections. Next steps of the process appear in the following diagram.

Figure 8: Research Onion (Saunders et al, 2007:102)



3.4.2 Research philosophy

Saunders, Lewis and Thornhill (2012) defined research philosophy as the core procedure of knowledge creation supplemented with an outline of what it is. Research philosopher Bryman and Bell (2011) establish agreement on phenomenology and realism and positivism as main epistemological positions.

According to positivism the researcher adopts a natural observational role to describe present day facts with unbiased science-based methods (Saunders et al., 2012). The research draws its information from academic literature sources. The research aims to expand a current conceptual framework which already exists for new application domains. The research evaluated particular constructs related to AIML adoption in pharmaceutical drug development through their dependencies among one another. Scientists employed this study under the positivist paradigm while conducting statistical tests to determine exact outcomes through scientific methods. Researchers evaluated linkages and their significance for developing a new theory in this field of research.

3.4.3 Methodological Choice: This research utilizes a quantitative methodology to rigorously confirm or test a hypothesis. By employing objective measurements and statistical validation, this method ensures the reliability and precision of the findings. Quantitative research enables a methodical examination of trends and patterns, enabling a distinct comparison of outcomes. Additionally, the use of statistical tools enhances the accuracy and repeatability of the study, ensuring that the outcomes can be replicated and verified in future research. This method is very good for management research since it helps to test hypotheses and provide strong proof to back up decision-making processes.

3.4.4 Research approaches

By applying hypothetico-deductive methodology to examine its research question, the given investigation has resorted to reductionism logic, as complex research quality has been reduced to an ordered system of variables that are able to exhibit possible causal fits (Saunders et al., 2012). Since the current literature provides ample information with regard to informing the inquiry, clearly states causal connections, and points at knowledge gaps to ensure the validity of the study, the hypothetico-deductive design was established as suitable (Chapter 2). Research investigators selected an inductive technique instead of deductive since it involves observing events followed by drawing inferences from accumulated research data (Malhotra et al., 2008).

Researchers primarily concentrate on developing theories and scenarios without pre-existing knowledge within this approach. The research draws its evidence from academic literature and aims to provide major insights into AIML implementation within drug development for pharmaceuticals therefore a deductive method was selected as the main approach.

3.4.5 Research strategies

Saunders et al. (2012) outline a list of strategies employed in carrying out a research. Within this framework, the researcher can choose between seven methodological paradigms: case studies, action research, ethnography, experiments, surveys, grounded theory and archive research. It seems impossible to put all of the explored tactics together to make research more valuable. The situation requires researchers to choose between different strategies. The research depended mainly on survey methodology to obtain data by collecting information from multiple research participants.

3.4.6 Time horizons

Saunders et al. (2012) indicate that researchers used the cross-sectional time horizon methodology for their investigation. Cross-sectional studies assess present situations using fixed temporal factors, so establishing a defined study period. To verify methodological influences within conceptual models' researchers must adopt a cross-sectional design strategy. The research started in July 2024.

3.4.7 Sources of data

In carrying out the current study, both primary and secondary sources of data were utilized which played an instrumental role at each analytic point of the data. Ethical protocols had to be followed to the letter at each data procurement phase.

3.4.7.1 Primary sources of data and assumptions

The next step in the research involved engaging the primary data collection process by designing a survey form to be distributed. The complete investigation led to personal LinkedIn contacts for each of the 1500 participants. The questionnaire existed on the Google Forms platform. All interview queries carefully responded that came before and after the survey while ensuring complete satisfaction of each respondent.

The gathering of basic data required four fundamental assumptions. The first assumption establishes that background facts about respondents obtained from credible web sources constitute valid and genuine information. The second assumption depended on honest answers to questions from technology and business executives who took part in the survey to get reliable expert opinions. The survey participants were expected to refrain from submitting two or more survey responses. The fourth research assumption maintained that participants would protect research confidentiality by keeping all data private while abstaining from sharing questions or answers with their colleagues.

3.4.7.2 Secondary sources of data

The study began with a review of primary information that was retrieved as secondary data through other reviews that were published. A secondary data is the information that has already been captured and can be acquired elsewhere. In chapter 2, indications as to the secondary data sources that were used in this study (see section 2.1.1) are clearly stated. The study was initiated by a comprehensive literature research via secondary resources in which the significant number of articles released in respectable world sources such as ISI Thomson, ABDC Journals, and various other resources was studied methodically. We have collected and read over 100 articles related to the topic and conducted in reliable sources: ProQuest, EBSCOhost, Google Scholar and DeepDyve one by one. These articles made the main research gaps more evident, putting focus on the limitations of this research and possible directions in the future research. Only papers published from 2017 to 2024 were considered. The literature review is a collection of most of these publications that have been put together in one place.

The research initiative began with a review of earlier researches in search of secondary information. Secondary data are those ones that have already been gathered and are available in the sources. In chapter 2, we identify the sources of secondary data that shall be utilized in our current study under section 2.1.1. In the first phase of study researchers performed a thorough literature review that was gathered using global sources such as, ISI Thomson, ABDC Journals, and others. This research examined more than 100 publications gathered from the reliable databases ProQuest and EBSCOhost and Google Scholar before DeepDyve. The publications explained significant research gaps by showing both existing research limitations and new paths for further study. Articles published between 2017 and 2024 made up the research material base. The literature review integrates findings from most peer-reviewed publications.

3.4.8 Population

The survey included respondents from different groups of people. The demographic for this study was made up of everyone who works in the pharmaceutical sector.

Figure 9: Population for the survey

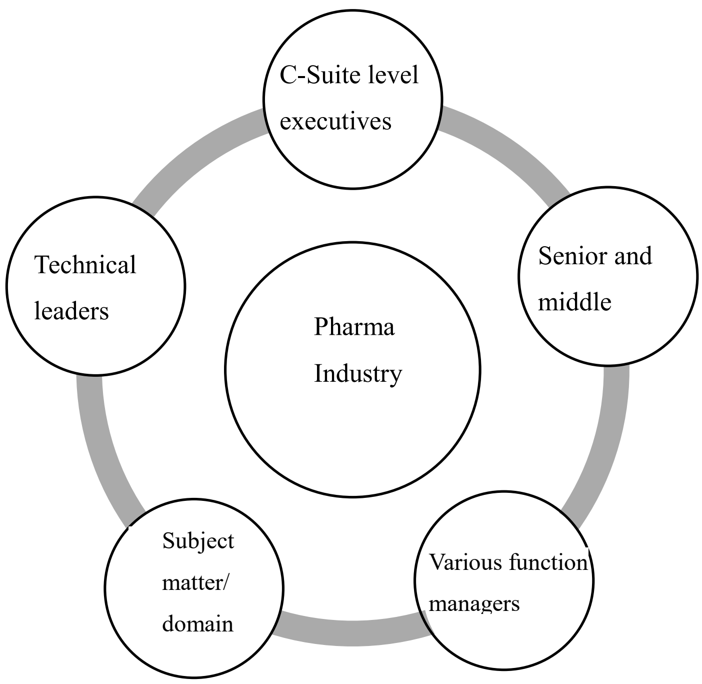


Figure 9 shows that the study's population included several positions or roles within the Pharmaceutical industry participated in the survey, including C-suite level executives, senior management, middle management, subject matter experts, domain experts, and technology leaders. This is a very good blend of survey participants to gain valuable insights.

3.4.9 Profile and demography of the respondents

The survey study included all necessary elements related to respondent backgrounds. Prospective participants underwent a rigorous screening process predicated on their credentials, including years of academic or industry experience, knowledge base, current title, research relevance, and projected contributions to the study. The participants who provided survey responses include individuals associated with the researcher and members obtained from reputable online sources whose information was taken as accurate during the background verification process.

The model attained reliability and validity via the quality and amount of the sample. The study pursued replies from distinguished pharmaceutical executives who worked for flagship companies operating across various regions according to Chapter 1. The research subject selection basis was their professional background extending from middle management to senior management positions. An extensive cross-section of participants completed the survey which included CEOs and CXOs from the firm along with Executives of the firm along with Stakeholders and all Managers and Associates from Firm departments along with acute expertise in both Pharma and AIML fields and beyond. Multiple respondents who completed the survey included data scientists along with clinical research associates and regulatory affairs associates and biostatistician professionals. The survey participants were veterans from the AI technology and pharmaceutical industries who had worked as chief marketing officers, chief technology officers, technical consultants, and strategists.

3.4.10 Sample size

This research study involved reaching about 1500 participants through online platform. The relevant and promising participants for individual contacts was successfully accessed through the business networking platform Linked . A thorough scan of selected candidate profiles confirmed their eligibility before responses were meticulously delivered. A detailed explanation fulfilled the objective of the survey. The survey maintained strong reassurances regarding confidentiality to all participants. The research collected 306 responses during its three-month duration.

To obtain a 95% confidence margin of error (confidence interval), the formula (Aczel et al., 2006) of the infinite population would require 95 percent confidence and a standard deviation of 0.5 in order to gain a reported margin of error of 6 percent. (confidence interval).

$$n = (z_{\alpha/2})^2 \sigma^2 / B^2$$

To get the appropriate sample size (n), use $Z\alpha/2$ (standard normal random variate) = 1.96, where the population standard deviation is 0.5 and B = 0.06 is the margin of error. So,

$$n = 1.96^2\, 0.5^2 / 0.06^2$$

$$n = 266.78$$

The sample of 306 people in this study is appropriate regarding its purposes. Standard practice requires the sample size of a survey to be 10 times greater than questions in its instrument with few exceptions of questions asking about demographics. According to this principle, the number of participants should not be lower than 240 since the study has a 24-question survey instrument.

The research benefits from an ample sample number of 306 which exceeds minimal requirements.

3.4.11 Statistical tools: Techniques and software

Statistical tests were used on the study framework relationships to generate specific model-building thesis findings. ADANCO 2.4 served as an analytical tool to produce essential information after survey data analysis. Structural equation modelling served as the analytical method to explain both measured variables and latent components.

Albers (2010) says that partial least squares (PLS) route modelling is the best statistical tool for looking at success variables. Numerous researchers from varying disciplines value PLS path modelling because it effectively handles classical factors alongside composites. According to Henseler & Dijkstra (2015), ADANCO version 2.4 was the software application that ran the hypothesis testing procedure using variance-based structural equation modelling approaches. Structural equation modelling using variance is made up of many different statistical methods, and ADANCO 2.4 is a significant contribution to these methods. Among the elements included in the constructed tables and figures were indicators of reliability along with validity measures. A measurement attains reliability when it shows precise and consistent results while validity indicates how well a measurement represents actual conditions according to (Cooper & Schindler, 2011). The analysis evaluated discriminatory validity through separate statistical findings of different conceptual constructs whereas convergent validity tested for the correlation between logically related construct measurements. For scientific investigations it is crucial to achieve higher levels of validity together with reliability. The assessment software verified that every independent model variable demonstrated no correlation between elements and operational independence.

Bootstrapping enabled researchers to adopt a non-parametric method of inference to determine whether the information on sample distribution provided some true details regarding the population distribution. Path coefficients, beta values, t-values and p-values were applied through acceptance and rejection of hypothesis in the hypothesis testing models.

3.4.12 The Rationale for Using Structural Equation Modelling

The established ways to look at and evaluate research material are still hard to grasp. The robust measurement standards limit adaptability because they treat measurement without errors. Structural equation modelling functions as a multivariate analysis approach because it offers versatile options through its flexible design and stands firm against errors or complexity (MacCallum & Austin, 2000). A successful investigative method requires both theoretical foundation and empirical evidence which creates obstacles for researchers who seek appropriate research methodologies. Multiple connected dependencies go through single analytic modelling within structural equation modelling thus making it the ideal choice for this study. Both the variables that were used in this analysis were exogenous (independent) and endogenous (dependent).

Research found out some direct and indirect relationships between both dependent variables and independent factors, as well as between the independent variables. Table 3 indicates the similar and different features of path analysis and regression.

Table 3: Similarities and Differences Between Regression and Path Analysis

Similarities		
Details	Regression	Path Analysis
Assumptions	Normal distribution	Multivariate normality
Linear relationship	Based on linear statistical models	Based on linear statistical models
Test of causality	Does not test causality	Does not test causality
Differences		
Details	Regression	Path Analysis
Variables	Can be dependent or independent	Can be dependent and independent
Error recognition	Assumes that measurement occurs without error	Explicitly specifies errors or unexplained variance
Flexibility	Inflexible	Highly flexible and comprehensive
Direct and indirect relationship	Not a convenient way to present direct and indirect relationships	A powerful and convenient way to present complex relationships, including direct and indirect relationships between variables, which are solved simultaneously to test model fit and estimate parameters

3.4.13 Questionnaire instrument

The evaluation of the conceptual model and data acquisition required implementing a research survey tool through questionnaires. Researchers designed an assessment tool based on questionnaires to obtain data during the pilot study and primary research phase. For both research studies the questionnaires maintained basic similarities but required alterations to accommodate the main research requirements. The final questionnaire containing 30 questions appeared on Google Forms for data collection. Appendix 3 contains the questionnaire worksheet which can be consulted.

In part 1 of the questionnaire, there was an introduction that highlighted the nature of the issue and the justification of the thesis. It mentioned that the survey will be voluntary and confidential and also the time remaining to complete the survey. The requesting of email addresses at the beginning of the survey was to allow thank you emails to the respondents and to trumpet the findings along with a copy of the thesis when it will be defended and published. The second section consisted of numerous parts in which there were a long run of questions related to one variable. Each of the variables either dependent or independent was measured by a number of questions with the use of a five-point Likert scale, which operated on the scale of a strong disagreement to an agreement.

The third part had some queries about the general information about the respondent like experience, education, gender, geography and occupation. The instrument here exquisitely integrated the diffusion of innovations theory by Rogers. The last part was a closing by leaving a note of thanks and confirming the situation that the survey was done and given.

Participants approval was also stated in building and distribution of the questionnaire such that both primary and secondary sources of data were also implied to exhibit their respective importance and were sought on a moral ground at various levels of research.

3.4.14 Design and construction of the survey research instrument

The research survey tool to obtain primary data in order to assess the conceptual model was a questionnaire. Studies reveal that the questionnaire has proved to be an influential as well as an orderly method of gathering credible information of respondents. In the proposed research, the data that forms the basis of the pilot study and the main study is the same in general although a questionnaire was designed specifically to collect it.

Mostly there were four distinct segments to the questionnaire. The introduction stage consisted of the research topic and the reason as to why it had to be done. It indicated the time that it would take to complete the survey and also guaranteed the confidentiality of the profile of the respondent and the information he/she provided.

The latter was the main body of the questionnaire itself. This segment was separated into numerous items, and each item was a different variable. The questionnaire had 4 independent variables and an independent variable. The questions concerning each of the variables were framed in the form of a multi-item scale and in particular, a five-point Likert scale as per earlier studies on digitalisation. The items on the scale included Strongly agree, Agree, Neutral, Disagree, and Strongly disagree.

The third part was on generic AI and Pharma related open ended questions. The theory of diffusion of innovations by Rogers was also incorporated in this section to determine whether the findings of this study survey would be consistent with the findings of this theory. Roger's theory of diffusion of innovations has 5 types of adopters as explained in 2.3 which are; innovators, early adopters, early majority, late majority and laggards. Such a survey tried to incorporate one additional category, which is, never adopt.

The fourth part of the questionnaire was more about demographic setting of the respondent such as; experience, education, current position or role in the organization, employment status, gender and geography were covered in this part. In this part, the respondents were thanked.

The total number of questions asked in the main study questionnaire to establish the main study question were 33 questions and included demographic information. The survey was available through the use of Google forms. This choice was preferred to any other means because it is easy to build, it does not involve any form of cost, it facilitates the process of distribution without much monitoring and it provides a consolidated spreadsheet to store and track the data.

The questionnaire worksheet has been designed on the basis of the gaps and the results which were achieved by the limitations / scope of future study and certified by the earlier literature and has been reflected in the Appendix section of this document. All the respondents were sent this.

3.4.15 Pilot study

The questionnaire was the first empirical research after conducting the literature review of the research topic. The paper tested the core theory explained in the body of literature in order to identify the relevancy of the base model, as well as to analyze the validity of the location of the survey in the given format. Pilot study results were used to narrow down and Invalidate the main study design.

The methodology employed in the pilot study was strongly relied on in the elaboration of the main study as to be explained in the following sections. A questionnaire was that was used as a survey instrument to gather the data in the pilot and main study as mentioned before. The advantages of the questionnaire method consist of fast responses, comparatively low-costs and high degree of control by respondents (Malhotra et al., 2008).

The pilot study involved pre-testing the questionnaire among targeted 50 people. The respondents contacted through the personal networking process met the demographic requirements that were put in place when approaching respondents in the baseline survey. The pilot research participants were experts in AIML and pharmaceutical sector, giving a full reflective implementation of various aspects of the population in a full-scale survey.

The pilot study gave a trial and subject to review the procedure of administering the questionnaire, the phrasing and the constructs located. At the end of the pilot study questionnaire there were open-ended questions to get any form of constructive feedback to improve. The respondents to be used had their comments sought where they were used to eliminate any trial and error or gaps in the questionnaire before any real fieldwork was initiated. This meant that the goal of the research was to incorporate pertinent responses to ensure a stronger methodology and that the foundational theory was scholarly sound. The results of the pilot study will not be regarded as conclusive and at this early period of the study it will be an oversimplification and generalisation of the results to the general population. It was not necessary to perform a demographic segmentation of the pilot research results since there was a small sample.

The analysis was carried out with the help of the Smart PLS software in the form of an exploratory factor analysis, all questions the loading estimate of which fell below 0.5 were revised or discarded in the questionnaire.

3.4.16 Main study: Sample design, assumptions, and data collection procedure

The core component of the empirical component of the research was the main study. The purpose of the pilot study was to test the imperative theory and the underlying procedure of deploying the survey, and the purpose of the main study was to establish reports on an in-depth analysis of the conceptual model, and also to conduct more helpings of the hypothesized relationships. The questionnaire prepared immediately following incorporation of the observations of the pilot study was then circulated in the main study. The significance of the scientific gathering of facts was attached to the process, and more so given the extensive complex statistical techniques that analyzed data.

A simple random sampling design was used to sample 1500 respondents on an extensive population of the survey, consisting of the stakeholders in the pharmaceutical industry worldwide. As calculated in section 3.4.10, a sample size of 306 met the requirements of adequacy in this research. The respondents were contacted through LinkedIn, or their email addresses and profiles on the websites of pharmaceutical companies. As described in section 3.4.9, there was a comprehensive background check on each recipient done to determine the robustness of the profile and the pertinence of the background. Achieving respondents in this study has been a zenith. The questionnaire was distributed through Google forms, and section 3.4.13 explains considerations that were the guiding principle of data gathering.

A structural equation model was employed in this thesis, wherein each relationship was associated with a particular hypothesis which can either prove or debunk the existence of a causal relationship. As a result, the nine relationships in the model tend to map onto the nine operational hypotheses, four of which are direct relations and the other five indirect ones.

The insights achieved during this step of the research ascended to the primary position relative to the thesis, as the backbone of the findings, and guided the package of recommendations and findings recorded in Chapter 5 and Chapter 6.

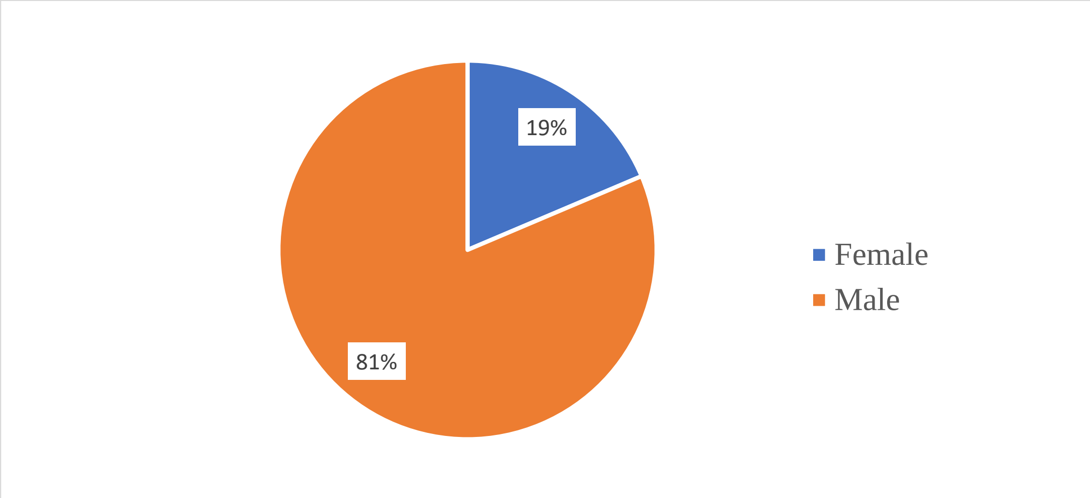
3.5 Demographic in the main survey

The demographic characteristic of the respondents in the main survey is given below. This section categorizes the demographics based on gender, professional experience, educational background, geographic location, current employment status, and participants' respective positions within the organization.

3.5.1 Gender

The survey was characterized by 81 % of answers given by male respondents and 19 % of answers gathered by female ones. Although the responses bias was in favor of the male gender, gender bias might not influence the research results.

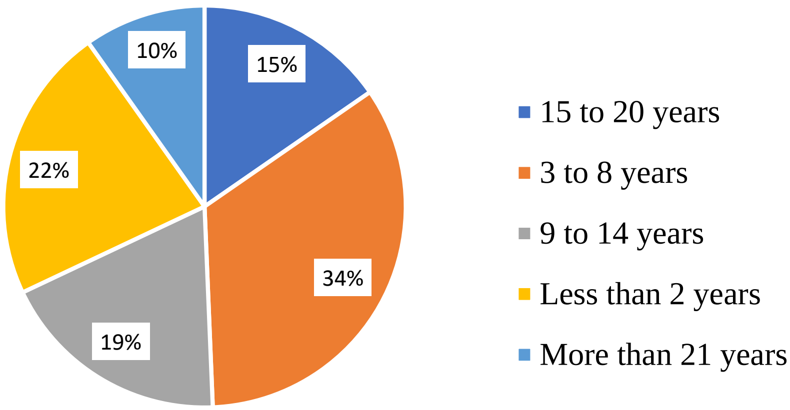
Figure 10: Demographic profile of the respondents: Gender



3.5.2 Experience

Respondents' relevant experience in Pharma, technology, AI, drug development was captured. The minimum age was 18 years and no maximum was given. The description of the experience is presented in Figure 11.

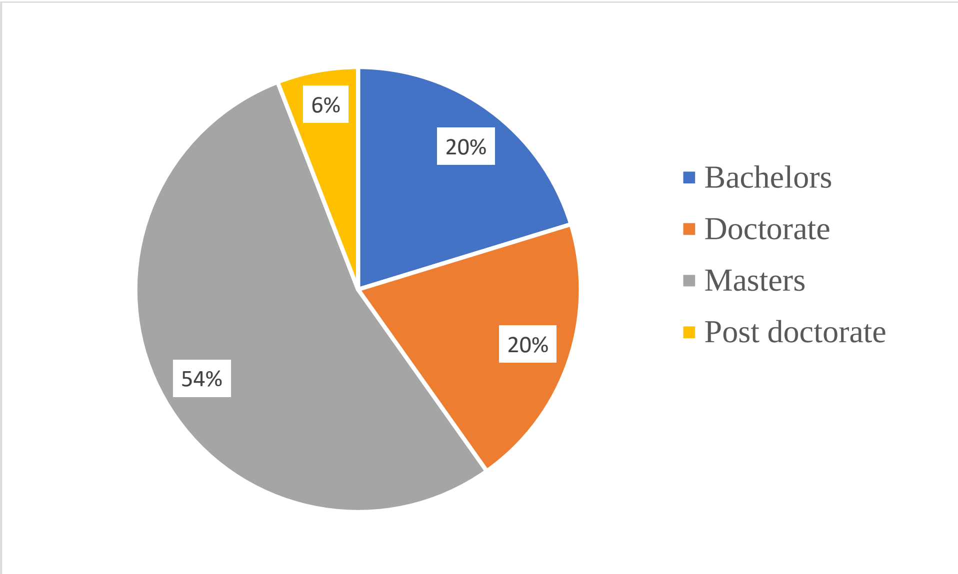
Figure 11: Demographic profile of the respondents: Experience



3.5.3 Educational level

Of the participants who responded to this questionnaire, 54% of the participants had a master's degree, 20 % held a bachelor's degree, another 20% were doctorate degree holders, and 6% had a post-doctorate degree. Figure 12 shows the academic level of the respondents.

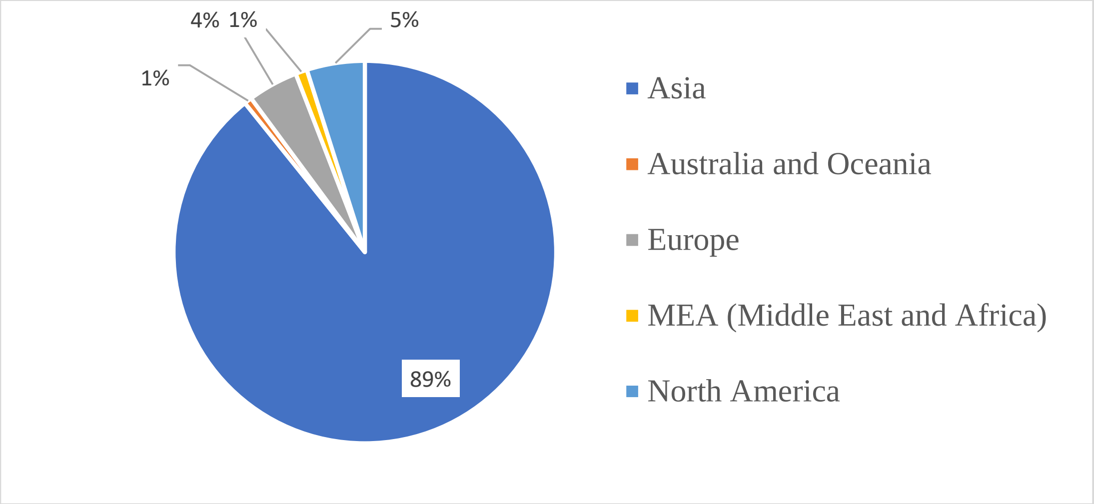
Figure 12: Demographic profile of the respondents: Education Level



3.5.4 Geography

The survey was emailed to all the relevant people within the pharmaceutical industry across Asia, North-America, Europe, the Middle East, Africa, Australia and Oceania. The geographical distribution of responders is shown in figure 13. Through the simple random sampling technique, around 1,000 people were randomly chosen in the population to be invited to take part in the survey. Three hundred six responses were obtained. In 2024, the survey was performed, and the response rate was approximately 33%.

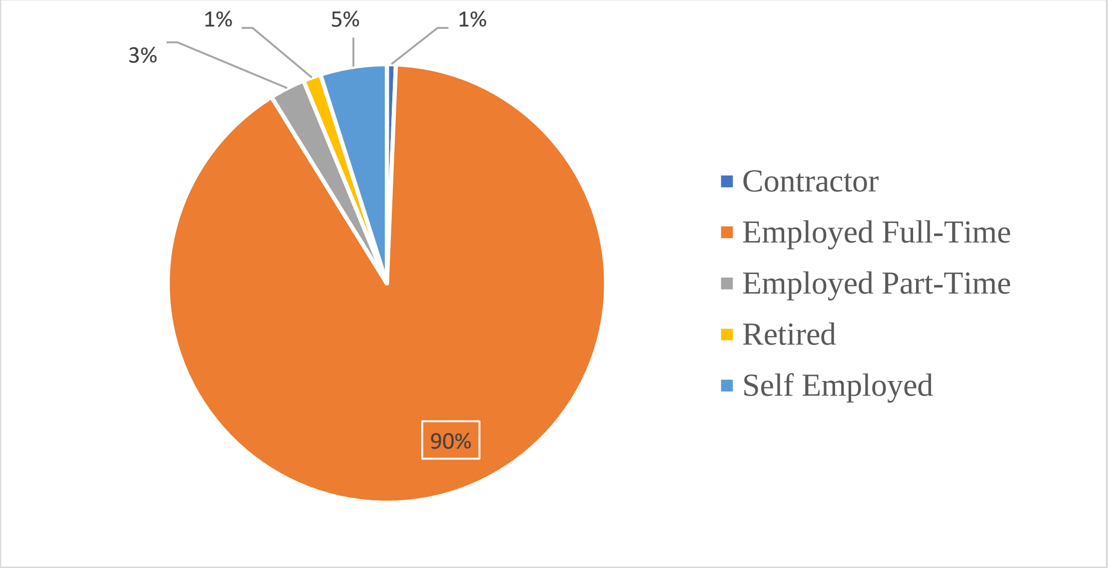
Figure 13: Demographic Profile of Respondents: Geography.



3.5.5 Current employment status

Ninety percent of the participants were working full-time, five percent were self-employed, and the other five percent were part-time employed, contractors, or retired. This majority guarantees favourable poll outcomes. Figure 14 illustrates the present job position of the respondents.

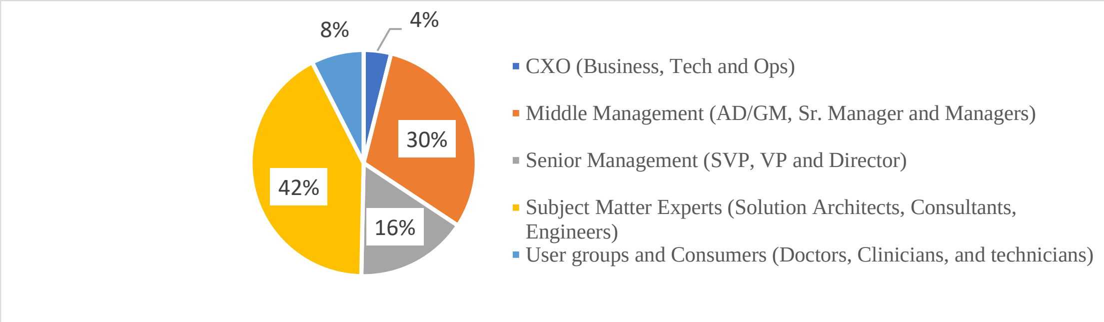
Figure 14: Demographic Profile of Respondents: Employment Status.



3.5.6 Position or role within the organization

Several positions or roles within the pharma industry participated in the survey, including C-suite level executives, senior management, middle management, subject matter experts, domain experts, technology leaders, doctors, clinicians, physicians, nurses and hospital administration. This is a very good blend of survey participants to gain valuable insights. Figure 15 illustrates respondents' occupations.

Figure 15.: Demographic Profile of Respondents: Position or Role Within the Organisation.



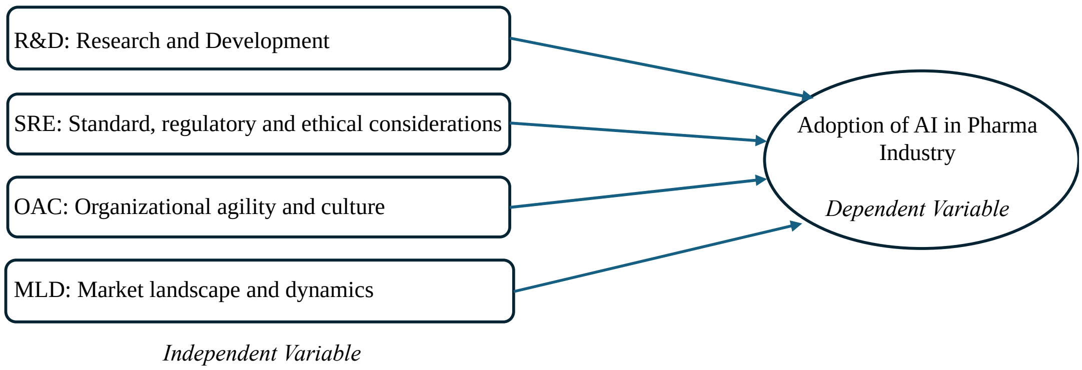
3.6 Research framework

A graphical representation has been developed to show a likely relationship between the independent and dependent variables. The model illustrated in Figure 16 is merely a theoretical framework and has not yet provided any evidence of the presence of the variable, its nature, severity, or its moderating/mediating roles.

The dependent variable is the adoption of AI. This is measured through the results of the study: Knowledge Creation, Compliance and Resilience, Organizational Adaptability, and Business Growth. Independent variables are the factors that influence the use of AI in pharmaceutical medication development. The stand-alone factors are likely to be Research and Development, Standards, Regulatory, and Ethical

Considerations, Organizational Agility and Culture, and Market Landscape and Dynamics.

Figure 16: Research Framework



3.7 Research merit & integrity

Research study aimed to enhance the state of academic literature and practice by filling the existing gaps in the explanation of the process of adopting AIML in drug development in the pharmaceutical industry. The literature review of AIML application in the development of pharmaceutical drugs was conducted in great detail and resulted in the development of research questions based on the findings of the review. This study was guided by the approach and design by a competent and experienced academic member at the University.

3.8 Informed consent

All the participants were emailed or contacted on LinkedIn and asked to participate. Participation in the survey was optional. Each profile of the potential participants was carefully analyzed to define the relevance of their replies. The participants were told about the purpose of the study at the beginning of the survey. The agreement of the participants involved informed consent and was part of the survey. There were measures to ensure that the persons who were made to take this survey were honest people who knew what they were discussing due to their qualifying backgrounds. Respondents were allowed to take enough time to answer the questions. The time taken by the respondents when responding was different; some of them responded instantly, whereas others took a long time of up to four reminders with tact. The reminders were not frequent and were in reverence of the need by the respondents to have leisure and privacy. They did not go away without solving the problem till the individual expressed satisfaction. No monetary rewards or the like was given out. The participants were not obliged and pressured to complete the survey. So, in all cases, the respondent's information was totally anonymous.

3.9 Risk management

In this study, any confidential information was not disclosed Questions that could give rise to negative emotions were avoided. Precautions were taken in order to avoid the incidence of seeking out sensitive information; the information has been conveyed in a clear language. The values of relevant religions and cultures were also respected as much as possible during the study.

3.10 Privacy and confidentiality

The confidentiality of the information and the safety of the information were emphasized and strictly guarded. The participants remained anonymous. Only email addresses were requested to send thank-you notes at the end of the study.

3.11 Conclusion

This chapter was meant to illustrate how to formulate hypotheses through the use of the study questions and aims. This chapter presented some of the aspects of research design and methodology such as the description of the demographics, respondent, data source, and consideration of ethical issues. The article described the design of the survey tool, i.e. the questionnaire and data collection methodology of the pilot and the major researches. The data were analysed using ADANCO 2.4 and this chapter discusses the decisions and procedures of utilizing the software. Chapter 4 will describe the data analysis of each of the nine hypotheses with an insight concerning the survey findings.

Chapter 4: Results

4.1 Introduction

The last chapter examined the research methodology, outlining the many techniques used in this study. It included the study ethics, the demographics of the respondents, and further specifics, as well as the methodological foundations of the survey. The hypotheses were scientifically formulated based on the research objectives and questions, and the techniques and statistical tools for both the pilot and main studies were emphasized.

This section focusses on data analysis and interpretation. The measurement model and the structural model, which includes statistical hypothesis testing, were evaluated to derive meaningful findings using the ADANCO 2.4 program for variance structural equation modelling. The analysis includes tables and figures showing information on construct reliability and discriminant validity along with measures for convergent validity and indicator multicollinearity as well as cross-loadings validity and hypothesis tests and analyses for inter-construct correlations and lastly loading estimates and t-values for determining each construct's determinants.

4.2 Structural Model

Structural model is used to understand the relationships between observed and latent variables. Structural modeling equation combines factor analysis and multiple regression to test complex theoretical models. It helps researchers to assess causal relationships and the overall fit of the model, ensuring that results are reliable and can be replicated (Hair and Black, 2012; Ullman, 2001; Jöreskog, 1978).

4.3 Measurement Model

The measurement model's objective is to elucidate the relationship between concepts and their corresponding measurements. Observables are referred to as indicators.

ADANCO 2.4 accommodates a diverse array of measuring model types (Dijkstra & Henseler, 2015).

1. Composite models
2. Common factor models (reflective measurement models)
3. MIMIC models (causal–formative measurement)
4. Single-indicator measurement
5. Categorical exogenous variables

The study utilized a reflecting model structure in its empirical method. Reported data and weighting techniques depend on the selection between reflective or composite measurement models. The minimum requirement for Partial least squares path modelling models is an observable indicator despite the selected measure for construct evaluation.

4.3.1 Construct Reliability

The assessment of construct reliability occurs through two types of metrics namely consistency reliability and split-half reliability which demonstrate instrument consistency across components and test-retest reliability which measures stability over time. The absence of systematic errors defines reliability while its level is indicated by the squared correlation value between known or unknown concepts and their associated measurement scores. The three build reliability quotients of ADANCO 2.4 show multiple indications across its different indications.

- Dijkstra–Henseler's rho (Dijkstra & Henseler, 2015)
- Composite dependability (Werts et al., 1978)
- Cronbach's alpha (Cronbach, 1951)

The reliability coefficients in Table 4 apply to all constructs included within the study.The model's reliability is verified through Dijkstra and Henseler (2015) criterion that indicates construct rho values above 0.7 indicate structural consistency and reliability where higher rho figures than 0.8 and 0.9 represent good and exceptional reliability respectively. The research marks a result exceeding 0.9 as exceptional (Jöreskog & Sörbom, 2006).

Table 4: *Construct reliability*

Construct	Dijkstra-Henseler's rho (ρ_A)	Jöreskog's rho (ρ_c)	Cronbach's alpha(α)
R&D	1.0000	0.9069	0.8714
SRE	1.0000	0.9411	0.9214
OAC	1.0000	0.9348	0.9127
MLD	1.0000	0.9026	0.8651
O&M	1.0000	0.9138	0.8740

Based on the criteria mentioned above for the three assessments, namely Dijkstra–Henseler's rho (ρA), Jöreskog's rho (ρc), and Cronbach's alpha (α), it is established that the dependability levels of this research are exceptional. According to Table 4, all five constructions have a Dijkstra–Henseler's rho of 1.0, indicating that the dependability of the constructs is exceptional. All five structures have a Jöreskog's rho (ρc) value above 0.9. The Jöreskog rho (ρc) method indicates exceptional dependability of the constructed measures. The dependability strength is exceptional because Cronbach's alpha (α) values exceed 0.8 including multiple values surpassing 0.9. The accepted minimum standard of Cronbach's alpha is 0.6 whereas values exceeding 0.70 indicate very reliable constructs (Taber, 2018).

4.3.2 Scale Validity

Validity assesses the effectiveness of a measuring instrument in evaluating a concept (Hair et al., 2011). A dependable metric does not inherently possess validity. A metric cannot be deemed legitimate if it lacks reliability. The previously stated tests confirmed the structures' dependability. This section evaluates the instrument's validity. Validity may be assessed by many methods. This section will examine three approaches for validating the scale: convergent validity, discriminant validity, and cross-loadings.

4.3.2.1 Convergent Validity

According to Campbell and Fiske (1959) convergent validity determines the relationship strength between measures of two constructs which share conceptual elements. The assessment of the model's convergent validity used AVE data sources. The AVE evaluates how much of the construct variance stems from accidental measurement errors in comparison to the actual construct dimensions. The threshold for evaluating this component is set at 0.5 according to Hair et al. (2011). Consequently, a construct with an AVE over 0.5 accounts for a significant proportion of the model's volatility.

Table 5: Construct Average Variance Extracted

Construct	Average variance extracted (AVE)
R&D	0.6609
SRE	0.7619
OAC	0.7417
MLD	0.6497
O&M	0.7261

Table 5 presents the AVE values for all components of the model. The model has convergent validity, as shown by values ranging from 0.6497 to 0.7619.

Researchers can verify convergent validity through by examining the statistical significance of indicators' maximum probability loadings that correspond to their respective latent variables (Anderson & Gerbing, 1988; Peter, 1981). A loading higher than 0.7 usually indicates sufficient validity when performing validity assessment. Twenty of the examined determining factors demonstrate loadings greater than 0.8 while four of them show a loading around 0.8.

Table 6: Convergent Validity Using Loadings

Indicator	R&D	SRE	OAC	MLD	O&M
R&D1	0.8303				
R&D2	0.8419				
R&D3	0.8196				
R&D4	0.7820				
R&D5	0.7893				
SRE1		0.8126			
SRE2		0.8991			
SRE3		0.8979			
SRE4		0.8790			
SRE5		0.8729			
OAC1			0.8335		
OAC2			0.8771		
OAC3			0.8867		
OAC4			0.8394		

OAC5	0.8681		
MLD1		0.7926	
MLD2		0.7932	
MLD3		0.8116	
MLD4		0.8180	
MLD5		0.8144	
O&M1			0.8312
O&M2			0.8464
O&M3			0.8804
O&M4			0.8497

It is thus acceptable to conclude that the model successfully meets the criteria for convergent validity without any question.

4.3.2.2 Discriminant Validity

Discriminant validity tests the true unconnected nature of theoretical constructs that should not link together (Campbell & Fiske, 1959). In principle different notions must demonstrate quantifiable separation from each other. ADANCO 2.4. employs the Fornell–Larcker criteria (Fornell & Larcker, 1981) to check reflective measurement discriminant validity. According to the model framework the Average Variance Extracted (AVE) value must be above the squared correlation measures shared with every construct under analysis. ADANCO 2.4 generates Table 7 showing Average Variance Extracted (AVE) on the main diagonal and the squared inter-construct correlations under the lower triangular section.

Table 7: Fornell and Larcker's Discriminant Validity

Construct	R&D	SRE	OAC	MLD	O&M
R&D	0.6609				
SRE	0.6565	0.7619			
OAC	0.6546	0.7025	0.7417		
MLD	0.6184	0.4872	0.5664	0.6497	
O&M	0.6231	0.5434	0.6438	0.6458	0.7261

Squared correlations; AVE in the diagonal.

The establishment of discriminant validity through data analysis requires the highest absolute column and row values to be on the diagonal. The establishment of this model demands that the Average Variance Extracted (AVE) value of the diagonal elements should surpass the mean calculation of non-diagonal rows and columns squared correlations. Such discriminant validity criteria exist in this model.

4.3.2.3 Validating the Scale Through Cross-loading

Cross-loading validation strengthens evidence for reliability and validity because it demonstrates consistent measurement of constructs through the instrument. The cross-loading matrix within ADANCO 2.4 contains relationships between both indicators and constructs. Table 8 shows that the determinants demonstrate higher loadings on their appropriate constructs (highlighted) than their possible connections to other constructs. The investigation verifies both the elements' distinct construction patterns along with the assessment's validity and demonstrates the instruments' freedom from cross-load biases.

Table 8: *Cross-loading Matrix*

Indicator	R&D	SRE	OAC	MLD	O&M
R&D1	**0.8303**	0.6624	0.6492	0.6351	0.6379

R&D2	**0.8419**	0.7237	0.6800	0.6627	0.6433
R&D3	**0.8196**	0.7442	0.7470	0.6413	0.6567
R&D4	**0.7820**	0.5631	0.5554	0.6027	0.6182
R&D5	**0.7893**	0.5988	0.6559	0.6533	0.6512
SRE1	0.6717	**0.8126**	0.6744	0.5511	0.5807
SRE2	0.7202	**0.8991**	0.7240	0.6208	0.6446
SRE3	0.7468	**0.8979**	0.7569	0.6220	0.6634
SRE4	0.6514	**0.8790**	0.7159	0.5831	0.6300
SRE5	0.7438	**0.8729**	0.7844	0.6674	0.6963
OAC1	0.6980	0.6828	**0.8335**	0.6402	0.6771
OAC2	0.6998	0.7455	**0.8771**	0.6366	0.6828
OAC3	0.7344	0.7669	**0.8867**	0.6865	0.7000
OAC4	0.6516	0.7260	**0.8394**	0.6010	0.6884
OAC5	0.6991	0.6869	**0.8681**	0.6754	0.7058
MLD1	0.6505	0.6194	0.6495	**0.7926**	0.6081
MLD2	0.6728	0.5711	0.5798	**0.7932**	0.6679
MLD3	0.5707	0.4944	0.5665	**0.8116**	0.6441
MLD4	0.6218	0.5449	0.5752	**0.8180**	0.6486
MLD5	0.6531	0.5830	0.6617	**0.8144**	0.6695
O&M1	0.6702	0.6046	0.6964	0.6665	**0.8312**
O&M2	0.6680	0.6400	0.6714	0.6975	**0.8464**
O&M3	0.6959	0.6398	0.6871	0.7053	**0.8804**

O&M4	0.6558	0.6275	0.6793	0.6690	**0.8497**

The model successfully met the criteria for validity, including convergent, discriminant, and cross-loading assessments. Consequently, the model has substantial reliability and validity.

4.3.3 Indicator Multicollinearity

In a multiple regression model, multicollinearity arises when there are significant correlations among the independent variables. The statistical evaluation of each independent variable predicative capacity becomes imprecise in the presence of multicollinearity. When multicollinearity exists both confidence intervals become more expansive while independent variable p-values grow less specific. Examples of multicollinearity encompass:

a. Two independent variables demonstrate a direct relationship with one another.

b. A set of independent variables deductively links to the original independent variable at its statistical maximum point.

One predictor variable becomes linearly predictable by its co-occurring independent variables in multiple regression models which produces multicollinearity. Several explanatory variables in multiple regression models exhibit linear correlation to the extent that multicollinearity occurs.

Tolerance and its inverse, the variance inflation factor (VIF), serve to identify multicollinearity. Certain studies indicate that a VIF of < 10 is acceptable, whereas others contend that the highest permissible value is 5 (Ringle et al., 2015).

Table 9: *Indicator Multicollinearity*

Indicator	R&D	SRE	OAC	MLD	O&M

R&D1	2.1237				
R&D2	2.3377				
R&D3	2.1476				
R&D4	1.8275				
R&D5	1.8107				
SRE1		2.0377			
SRE2		3.7209			
SRE3		3.6891			
SRE4		2.9599			
SRE5		2.7570			
OAC1			2.2846		
OAC2			2.9171		
OAC3			3.0939		
OAC4			2.3275		
OAC5			2.6736		
MLD1				1.8994	
MLD2				1.8989	
MLD3				1.9702	
MLD4				2.0620	
MLD5				2.0714	
O&M1					1.9522
O&M2					2.1048

O&M3	2.6205
O&M4	2.2504

Variance inflation factors (VIF)

Table 9 indicates that the VIF values for all constructions remain under the acceptable threshold of 5. Therefore, the test verifies the absence of multicollinearity in the model.

4.3.4 Inter-construct Correlations

The inter-construct correlation analysis shows the calculated correlations between different constructs. The presented Table 10 displays the bottom right quadrant of the construct inter-relationship matrix for symmetry purposes. Formulated correlations between constructs do not necessarily need to match correlation patterns between their component indicator scores. This study manually adjusted reliability measurements in the research to values different from one.

Table 10

Inter-construct Correlations

Construct	R&D	SRE	OAC	MLD	O&M
R&D	1.0000				
SRE	0.8103	1.0000			
OAC	0.8091	0.8381	1.0000		
MLD	0.7864	0.6980	0.7526	1.0000	
O&M	0.7894	0.7372	0.8024	0.8036	1.0000

Inter-construct correlations clearly explain the process of developing multiple regression models. Correlation coefficients over 0.5 between constructs indicate a strong structural model and many significant mediations.

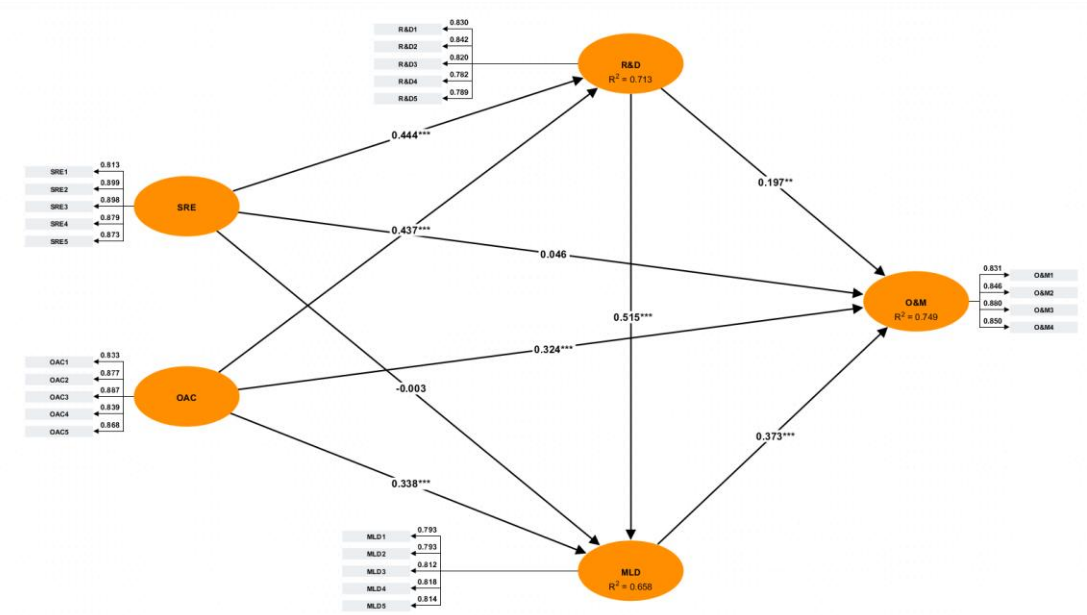
4.4 Structural Equation model

The structural model links components of exogenous and endogenous factors through their internal relationships. Information values from outside sources produce the external structures in the model framework. Arrows within the structural model do not point towards external constructs because this model does not define them through other inner model constructs.

The endogenous constructions may be elucidated by the model's other components. Each endogenous component in the structural model must be indicated by at least one directional arrow. Ovals represent structures, whereas arrows denote links in the model network. A linear association is often assumed among the different factors.

Scientific studies emphasizing path correlations frequently focus on magnitude and importance because all residuals have uncorrelated status, yet the constructed structural model must follow ADANCO 2.4 for recursing purposes. The structural models consist of several independent components with unique designations. Figure 17 displays the path coefficients which generated the structural model using ADANCO 2.4 in an empirical study. The Appendix offers a comprehensive examination.

Figure 17: Structural Equation Model



Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.

4.4.1 Coefficient of determination

Figure 17 reveals the structural model while showing the values of each path coefficient**.** The adoption of AI in the pharmaceutical industry is the dependent variable. The independent variables in this model account for 74.9% of the total variability in the latent variable according to the R^2 value measured at 0.749. The obtained value stands as an impressive achievement for PLS regression models (Henseler & Fassott, 2010). According to Hair et al. (2011) thesis on hypothesis testing and path coefficient measurement it is vital to conduct t-tests to verify statistical relationships between model variables. Two-tailed t-tests yielded statistical outcomes which are displayed in Table 11 at the 10% and 5% and 1% levels of significance. The findings in Table 11 allow researchers to determine statistical significance through t-values and p-values.

Table 11

Measurement of T-values

Significance	T-values	Decision
p > 0.10	t < 1.65	Not significant
0.10 > p > 0.05	1.65 < t < 1.96	Moderate
0.05 > p > 0.01	1.96 < t < 2.59	Significant
p < 0.01	t > 2.59	Very significant

Nine hypotheses were developed in the course of this study. To assess the validity of the hypotheses, each was examined against documented t-values of the independent and dependent variables. A bootstrapping strategy was used for simulating uncertain population data (Efron, 1987).

Table 12

Direct Effects Inference

	Standard bootstrap results						Percentile bootstrap quantiles			
Effect	Original coefficient	Mean value	Standard error	t-value	p-value (2-sided)	p-value (1-sided)	0.5%	2.5%	97.5%	99.5%
R&D -> O&M	0.3888	0.3876	0.0648	**5.9974**	0.0000	0.0000	0.2236	0.2600	0.5155	0.5614
SRE -> O&M	0.2173	0.2180	0.0649	**3.3507**	0.0008	0.0004	0.0459	0.0925	0.3476	0.3867
OAC -> O&M	0.6203	0.6165	0.0643	**9.6509**	0.0000	0.0000	0.4459	0.4828	0.7372	0.7760
MLD -> O&M	0.3730	0.3730	0.0546	**6.8340**	0.0000	0.0000	0.2353	0.2689	0.4812	0.5214

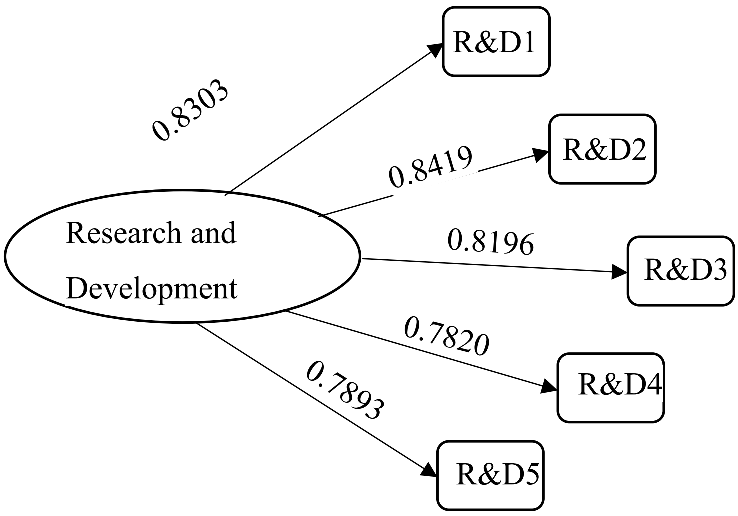
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.

4.4.2 Direct Effects

4.4.2.1 Hypotheses Tested for Research Question 1 on Research and Development

A research literature assessment demonstrates that pharma companies use Research and Development capabilities as a factor in their adoption of AI. The reflective model included Five factors as research development indicators which are illustrated in Figure 18 and Table 13. Figure 17 depicts the structural equation model through which the study answers its questions and demonstrates how the five factors generate their associated constructs. The structural equation model presents loading estimates along with t-values to demonstrate construct importance.

Figure 18: Loading Estimates of the Determinants of Research and Development (R&D)



Bullmore et al. (2000) established that independent variable influences rated between 0.5 to 0.8 depict a moderate effect (Wright, 1934). Table 13 contains a summary of Research and Development determinant hypotheses which are supported by Figure 18.

Table 13

Hypotheses Tested for the Determinants of Research and Development (R&D)

Research question 1: How does adoption of AI technologies in drug development influences the outcome of Research and Development processes in pharmaceutical industry? Hypothesis 1 (H1): Research and development significantly influences AI adoption in drug development in pharma industry through data quality and quantity, technological advancement, verification and validation, environmental sustainability and resilience, interpretability and explainability				
No.	Determinant hypotheses	Loadings > 0.8 strong 0.5 < L < 0.8 moderate	T-values t > 2.59 strongly significant	Inference on loadings
H1a	Data quality and quantity is a significant and distinct determinant of the construct Research & development (R&D1)	0.8303	25.8087	Strong
H1b	Technological advancement is a significant and distinct determinant of the construct Research & development (R&D2)	0.8419	25.2724	Strong
H1c	Verification and Validation is a significant and distinct determinant of the construct Research & development (R&D3)	0.8196	22.5057	Strong
H1d	Environmental Sustainability and Resilience is a significant and distinct determinant of the construct Research & development (R&D4)	0.7820	23.6254	Moderate

H1e	Interpretability and Explainability is a significant and distinct determinant of the construct Research & development (R&D5)	0.7893	24.4496	Moderate

H1: Research and development significantly influence AI adoption in drug development in pharma industry through data quality and quantity, technological advancement, verification and validation, environmental sustainability and resilience, interpretability and explainability.

Figure 19: Influence of Research and Development (R&D) on AI adaption (O&M)

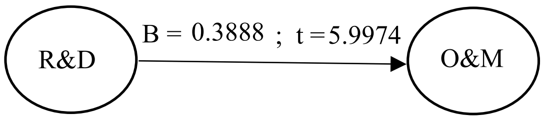
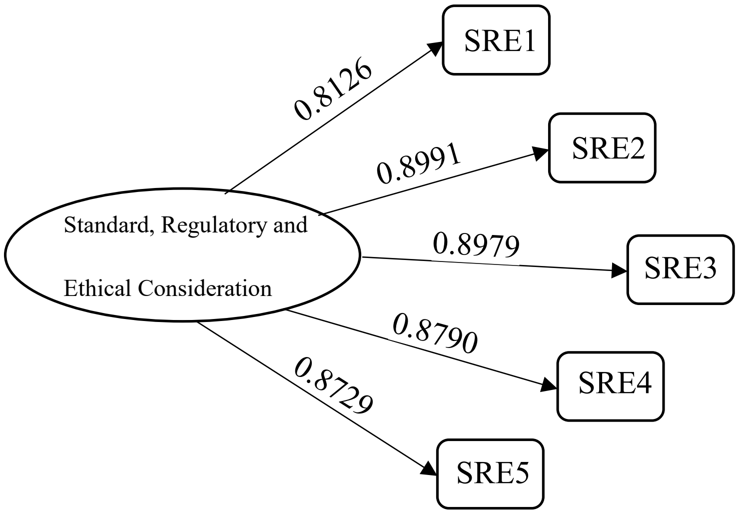


Table 13 demonstrates a very significant correlation between research and development and AI adoption, shown by a t-value of 5.9974. The effect is favourable, as the path coefficient of 0.3888 suggests that an enhancement in Research and Development related to technology is likely to elevate AI usage within the pharmaceutical industry. Consequently, the first hypothesis (H1) is validated at a 1% significance threshold (t > 2.59), indicating that Research and Development substantially impacts AI adoption within the pharmaceutical industry.

4.4.2.2 Hypotheses Tested for Research Question 2 on Standard, Regulatory and Ethical Considerations

A comprehensive literature review found standard, regulatory, and ethical considerations as a factor affecting AI adoption in the pharmaceutical industry. Five factors were proposed to assess Standards, Regulatory, and Ethical aspects using a reflective manner. The structural equation model (refer to Figure 17) offered a comprehensive perspective that illustrated responses to the research subject and the significance of each of the five dimensions in affecting their corresponding constructs. The loading estimates and t-values of the structural equation model indicate their relevance.

Figure 20: Loading Estimates of the Determinants of Standard, Regulatory and Ethical Consideration (SRE)



The authors of Bullmore et al. (2000) state that an independent variable influence passes regulatory thresholds when its loading numbers fall between 0.5 to 0.8 but becomes significant if its value exceeds 0.8 (Wright, 1934). The summary in Table 14 demonstrates the hypothesis results for Standards, Regulatory and Ethical determinants based on Figure 20.

Table 14
Hypotheses Tested for the Determinants of Standard, Regulatory and Ethical Consideration (SRE)

Research question 2: How do standards, regulations, and ethical considerations impact the adoption and implementation of AI technologies in drug development?

Hypothesis 2 (H2): Standard, Regulatory and Ethical Considerations significantly influences AI adoption in drug development in pharma industry through intellectual property protection, ethical consideration, data privacy and security, regulatory approvals and risk management, interoperability and data standards.

No.	Determinant hypotheses	Loadings > 0.8 strong 0.5 < L < 0.8 moderate	T-values t > 2.59 strongly significant	Inference on loadings
H2a	Intellectual property protection is a significant and distinct determinant of the construct Std & Reg and Ethical Considerations (SRE1)	0.8126	23.5582	Strong
H2b	Ethical consideration is a significant and distinct determinant of the construct Std & Reg and Ethical Consideration (SRE2)	0.8991	45.1633	Strong
H2c	Data privacy and security is a significant and distinct determinant of the construct Std & Reg and Ethical Consideration (SRE3)	0.8979	44.3235	Strong
H2d	Regulatory approvals and Risk Management is a significant and distinct determinant of the construct Std & Reg and Ethical Consideration (SRE4)	0.8790	42.9638	Strong

H2e	Interoperability and Data standards is a significant and distinct determinant of the construct Std & Reg and Ethical Consideration (SRE5)	0.8729	32.2597	Strong

Hypothesis 2 (H2): Standard, Regulatory and Ethical Considerations significantly influences AI adoption in drug development in pharma industry through intellectual property protection, ethical consideration, data privacy and security, regulatory approvals and risk management, interoperability and data standards.

Figure 21: Influence of Standard, Regulatory and Ethical Considerations (SRE) on AI Adoption (O&M)

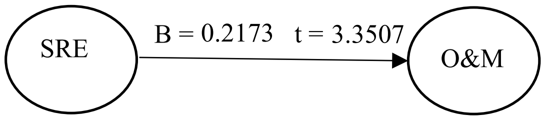
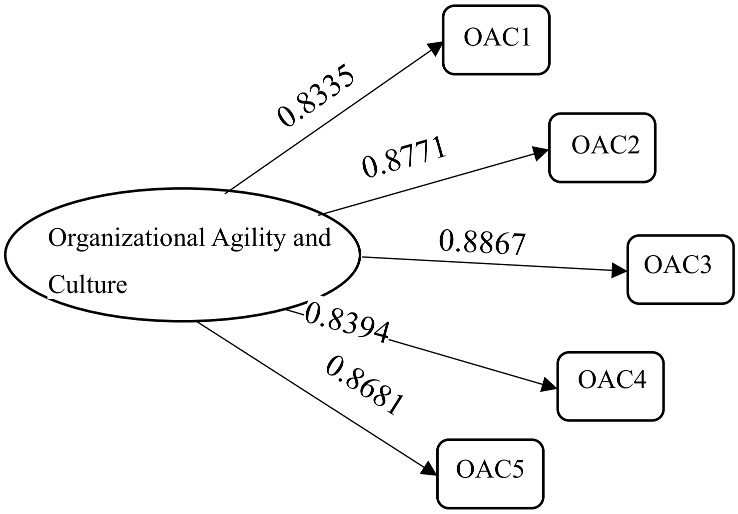


Table 14 indicates a strong relationship for three of five sub-independent determinants whereas moderate with two of five sub-independent determinants between Standards, Regulatory and Ethical considerations and AI adoption, with a t-value of 3.3507. This influence is positive, as the path coefficient $\beta = 0.2173$ indicates that an increase in Standards, Regulatory and Ethical considerations is likely to increase AI adoption in the Pharma industry. Therefore, the second hypothesis (H2) is accepted at a 1% significance level ($t > 2.59$), and it can be determined that Standards, Regulatory and Ethical considerations very significantly influence AI adoption in the Pharma industry.

4.4.2.3 Hypotheses Tested for Research Question 3 on Organizational Agility and Culture:

Organisational agility and culture is a factor impacting AI adoption in the pharmaceutical industry, as identified in the research study. An introspective approach yielded five criteria for assessing Organisational Agility and Culture. The comprehensive view of the structural equation model emphasised the importance of all five dimensions and their corresponding structures. The loading estimates and t-values of the structural equation model validated their relevance.

Figure 22: Loading Estimates of the Determinants of Organizational Agility and Culture (OAC)



Bullmore et al. (2000) established that independent variable influence is moderate when loading values fall between 0.5 and 0.8 (Wright, 1934). Significant effect is indicated by loading values greater than 0.8. The determinants' hypotheses for Organizational Agility and Culture receive their testing base in Figure 22 and Table 15 provides a summary.

Table 15
Hypotheses Tested for the Determinants of Organizational Agility and Culture (OAC)

Research question 3: What role does organizational culture play in facilitating the integration of AI technologies in drug development within pharmaceutical companies? **Hypothesis 3 (H3):** Organizational Agility and Culture significantly influences AI adoption in drug development in pharma industry through vision & mission, leadership and governance, talent management, collaboration, change management.				
No.	Determinant hypotheses	Loadings > 0.8 strong 0.5 < L < 0.8 moderate	T-values t > 2.59 strongly significant	Inference on loadings
H3a	Vision & Mission is a significant and distinct determinant of the construct Organizational Agility and Culture	0.8335	26.6711	Strong
H3b	Leadership and Governance is a significant and distinct determinant of the construct Organizational Agility and Culture	0.8771	38.3758	Strong
H3c	Talent Management is a significant and distinct determinant of the construct Organizational Agility and Culture	0.8867	40.6291	Strong
H3d	Collaboration is a significant and distinct determinant of the construct Organizational Agility and Culture	0.8394	25.1964	Strong
H3e	Change management is a significant and distinct determinant of the construct Organizational Agility and Culture	0.8681	33.4468	Strong

Hypothesis 3: Organizational Agility and Culture significantly influences AI adoption in drug development in pharma industry through vision & mission, leadership and governance, talent management, collaboration, change management.

Figure 23: The Influence of Organizational Agility and Culture (OAC) on AI Adoption (O&M)

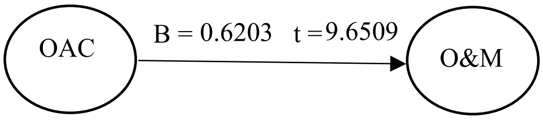


Table 15 indicates a very significant relationship between Organizational Agility and Culture and AI adoption, with a t-value of 9.6509. The influence of Organizational The integration of agility and culture is expected to enhance AI adoption within the pharmaceutical sector. Consequently, this hypothesis is accepted at a 1% significance level ($t > 2.59$), leading to the conclusion that Organisational Agility and Culture strongly affect AI adoption within the pharmaceutical industry.

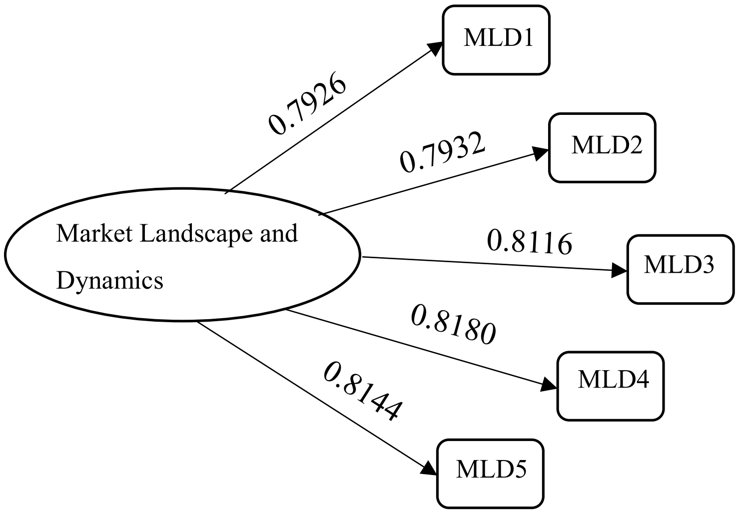
The significance of H3 thus drives the importance of Organizational Agility and Culture for effective AI adoption in the pharma industry.

4.4.2.4 Hypotheses Tested for Research Question 4 on Market Landscape and Dynamics

Market landscape and dynamics was identified as a significant element driving AI adoption in the pharmaceutical business. Figure 24 and Table 16 illustrate a reflective model that proposes five parameters for assessing the impact of Market Landscape and Dynamics on AI adoption within the pharmaceutical industry. Figure 17 illustrates the structural equation model, which addressed the research question and emphasised the importance of the five factors in generating the related constructs.

The loading estimates and t-values of the structural equation model underscore their relevance.

Figure 24: Loading Estimates of the Determinants of Market Landscape and Dynamics (MLD)



The researchers at Bullmore et al. (2000) emphasized that variable loading values between 0.5 to 0.8 represent modest independent variable effects and loading values above 0.8 indicate substantial effects according to Wright (1934). A summary of AI deployment hypotheses evaluation appears in Figure 24 of Table 16.

Table 16

Hypotheses Tested for the Determinants of Market Landscape and Dynamics (MLD)

Research question 4: How does market dynamics influence the organizational readiness to effectively deploy AI technologies in drug development within pharmaceutical industry?
Hypothesis 4 (H4): Market Landscape and Dynamics significantly influences AI adoption in drug development in pharma industry through cost & investments, patient

centricity and personalization, market size and growth, market disruption and business model innovation, market perception and stigma.				
No.	Determinant hypotheses	Loadings > 0.8 strong 0.5 < L < 0.8 moderate	T-values t > 2.59 strongly significant	Inference on loadings
H4a	Cost & Investments is a significant and distinct determinant of the construct Market Landscape and Dynamics (MLD1)	0.7926	23.5297	Moderate
H4b	Patient centricity and personalization is a significant and distinct determinant of the construct Market Landscape and Dynamics (MLD2)	0.7932	25.3192	Moderate
H4c	Market size and growth potential is a significant and distinct determinant of the construct Market Landscape and Dynamics (MLD3)	0.8116	32.7114	Strong
H4d	Market disruption and business model innovation is a significant and distinct determinant of the construct Market Landscape and Dynamics (MLD4)	0.8180	31.8800	Strong
H4e	Market perception and Stigma is a significant and distinct determinant of the construct Market Landscape and Dynamics (MLD5)	0.8144	31.2711	Strong

H4: Market Landscape and Dynamics significantly influences AI adoption in drug development in pharma industry through cost & investments, patient centricity and personalization, market size and growth, market disruption and business model innovation, market perception and stigma.

Figure 25: *Influence of* Market Landscape and Dynamics *(MLD) on AI Adoption (O&M)*

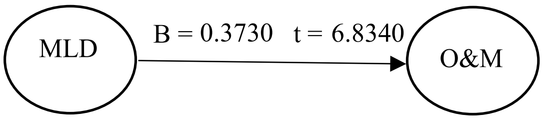


Table 16 demonstrates a substantial correlation between Market Landscape and Dynamics and AI adoption, shown by a t-value of 6.8340. Consequently, the Market Landscape and Dynamics is expected to enhance AI adoption among the pharmaceutical industry. This hypothesis is accepted at a 1% significance level ($t > 2.59$), indicating that Market Landscape and Dynamics significantly influence AI adoption in the pharmaceutical industry.

4.4.2.5 Market Landscape and Dynamics Mediates the Impact of Research and Development on AI adoption

Hypothesis 6: Market Landscape and Dynamics mediates the impact of Research and Development on AI Adoption (H5).

Figure 26: *R&D-MLD-O&M (Mediating Effect*

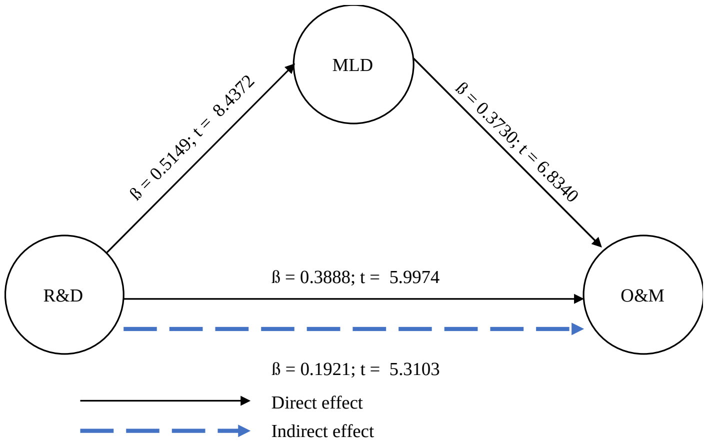


Table 17

R&D-MLD-O&M (Mediating Effect)

		β	t	SE	Effect
R&D	MLD	0.5149	8.4372	0.0610	Positive and very significant
MLD	O&M	0.3730	6.8340	0.0546	Positive and very significant
R&D	O&M	0.3888	5.9974	0.0648	Positive and very significant
β	0.1921	Positive			
t	5.3103	t > 2.59, very significant			
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.					

a. Test of mediation: The path coefficient from Research and Development to Market Landscape and Dynamics (t = 8.4372) is supported at a 1% significance level (t > 2.59). The path coefficient from Market Landscape and Dynamics to O&M (t = 6.8340) is supported at a 1% significance level (t > 2.59).

b. Type of mediation: The findings indicate that the path coefficient from the independent variable to the dependent variable, together with the t-value (>2.59), is very significant. Consequently, partial mediation is present.

Thus, the hypothesis (H5) is supported: Market Landscape and Dynamics mediates the impact of Research and Development on O&M (H5)

4.4.2.6 Research and Development Mediates the Impact of Standards, Regulatory and Ethical considerations on AI Adoption

Hypothesis 6: Research and Development mediates the impact of Standards, Regulatory and Ethical considerations on AI adoption (O&M) in the Pharma industry (H6).

Figure 27: *SRE-R&D-O&M (Mediating Effect)*

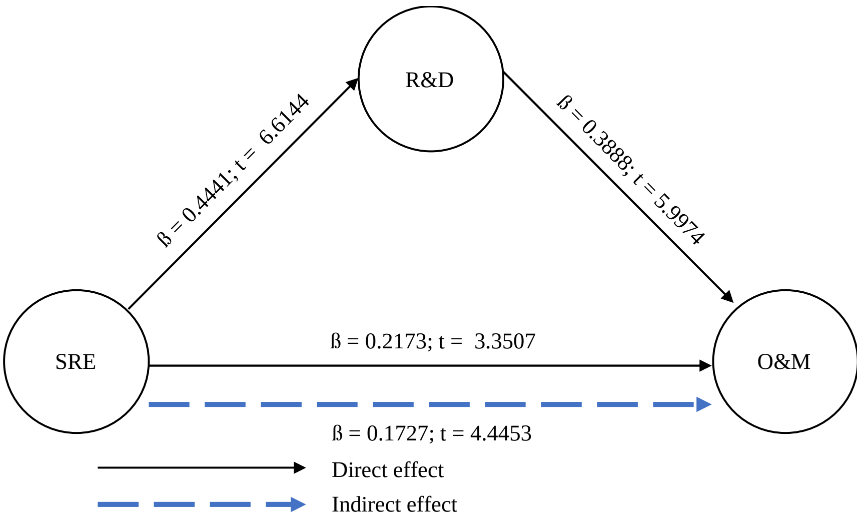


Table 18

SRE-R&D-O&M (Mediating Effect)

		β	t	SE	Effect

SRE	R&D	0.4441	6.6144	0.0671	Positive and very significant
R&D	O&M	0.3888	5.9974	0.0648	Positive and very significant
SRE	O&M	0.2173	3.3507	0.0649	Positive and very significant
β	0.1727	Positive			
t	4.4453	t > 2.59, very significant			
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.					

a. Test of mediation: The path coefficient from Standards, Regulatory, and Ethical issues to Research and Development (t = 6.6144) is validated at a 1% significance level (t > 2.59). The path coefficient from R&D to O&M (t = 5.9974) is validated at a 1% significance level (t > 2.59). Therefore, it may be inferred that mediation is present.

a. Type of mediation: The findings indicate that the path coefficient from the independent variable to the dependent variable and the t-value (>2.59) are very significant. Consequently, partial mediation is present.

Consequently, the hypothesis (H6) is validated: Research and Development mediates the influence of Standards, Regulatory, and Ethical issues on AI adoption within the pharmaceutical industry.

4.4.2.7 Market Landscape and Dynamics Mediates the Impact of Standards, Regulatory and Ethical considerations on AI Adoption

Hypothesis 7: Market Landscape and Dynamics mediates the impacts of Standards, Regulatory and Ethical considerations on AI adoption (H7).

Figure 28: *SRE-MLD-O&M (Mediating Effect)*

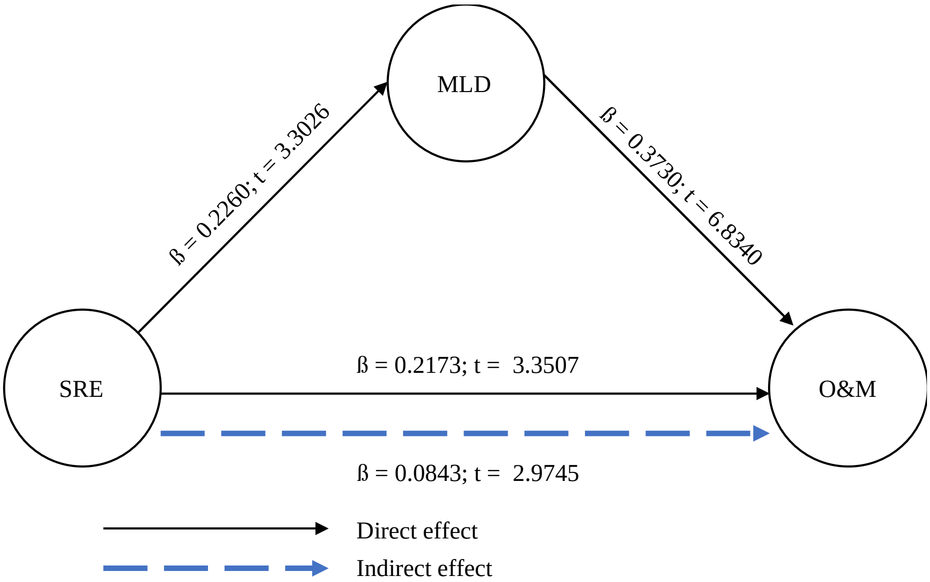


Table 19

SRE-MLD-O&M (Mediating Effect)

		β	t	SE	Effect
SRE	MLD	0.2260	3.3026	0.0684	Positive and very significant
MLD	O&M	0.3730	6.8340	0.0546	Positive and very significant
SRE	O&M	0.2173	3.3507	0.0649	Positive and very significant
β	0.0843	Positive			
t	2.9745	t > 1.96, significant			
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.					

a. Test of mediation: The path coefficient from Standards, Regulatory and Ethical considerations to Market Landscape and Dynamics ($t = 3.3026$) is supported at a 1% significance level ($t > 2.59$). The path coefficient from Market Landscape and Dynamics to O&M ($t = 6.8340$) is supported at a 1% significance level ($t > 2.59$). Hence, it can be concluded that mediation exists.

b. Type of mediation: The findings indicate that the path coefficient from the independent variable to the dependent variable and the t-value (>1.96) are statistically significant. Consequently, partial mediation is present.

Thus, the hypothesis (H7) is supported: Market Landscape and Dynamics mediates the impact of Standards, Regulatory and Ethical considerations on AI adoption.

4.4.2.8 Research and Development Mediates the Impact of Organizational Agility and Culture on AI Adoption

Hypothesis 8: Research and Development mediates the impact of Organizational Agility and Culture on AI adoption (H8).

Figure 29: OAC - R&D – O&M (Mediating Effect)

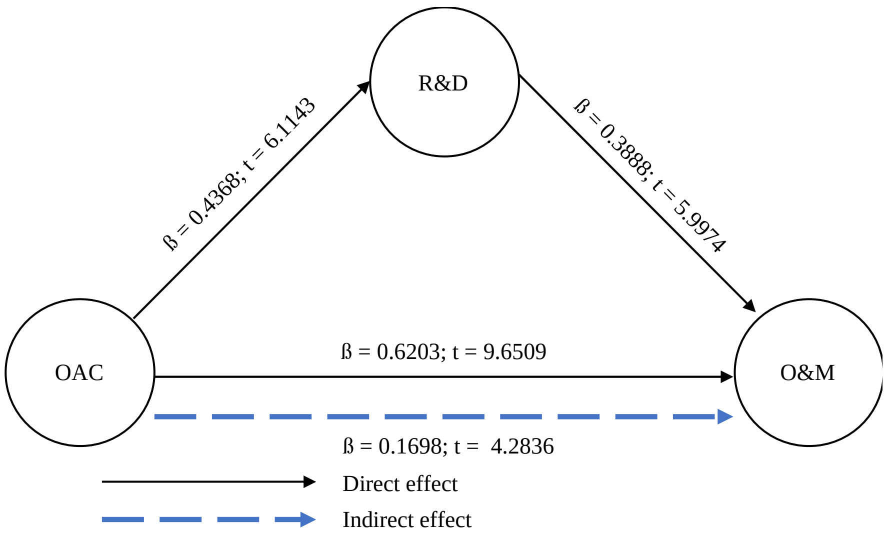


Table 20

OAC - R&D – O&M

		β	t	SE	Effect
OAC	R&D	0.4368	6.1143	0.0714	Positive and very significant
R&D	O&M	0.3888	5.9974	0.0648	Positive and very significant
OAC	O&M	0.6203	9.6509	0.0643	Positive and very significant
β	0.1698	Positive			
t	4.2836	t > 2.59, significant			
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.					

a. Mediation analysis: The path coefficient from Organisational Agility and Culture to Research and Development ($t = 6.1143$) is validated at a 1% significance level ($t > 2.59$). The path coefficient from Research and

Development to O&M (t = 5.9974) is validated at a 1% significance level (t > 2.59). Therefore, it may be inferred that mediation is present.

a. Type of mediation: The findings indicate that the path coefficient from the independent variable to the dependent variable and the t-value (>2.59) are very significant. Therefore, partial mediation is present.

Thus, the hypothesis (H8) is supported: Research and Development mediates the impact of Organizational Agility and Culture on AI adoption.

4.4.2.9 Market Landscape and Dynamics Mediates the Impact of Organizational Agility and Culture on AI adoption

Hypothesis 9: Business intelligence mediates the impact of DS on PM (H9).

Figure 30: OAC – MLD – O&M (Mediating Effect)

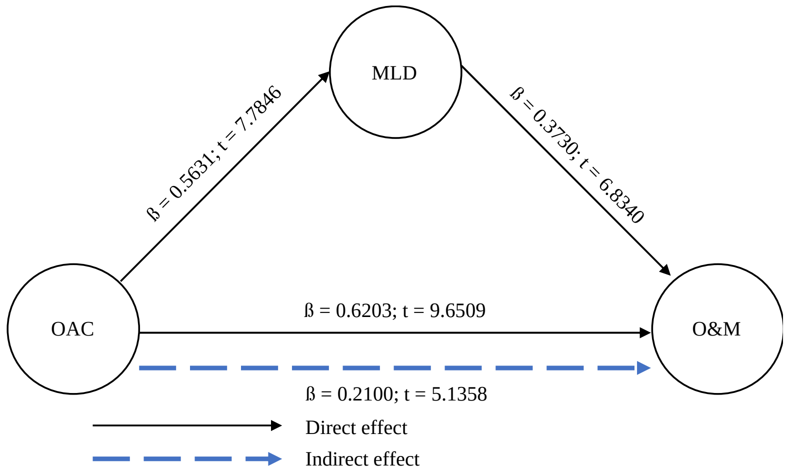


Table 21

OAC – MLD – O&M

		β	t	SE	Effect
OAC	MLD	0.5631	7.7846	0.0723	Positive and very significant
MLD	O&M	0.3730	6.8340	0.0546	Positive and very significant
OAC	O&M	0.6203	9.6509	0.0643	Positive and very significant
β	0.2100	Positive			
t	5.1358	t > 2.59, very significant			
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.					

a. Test of mediation: The path coefficient from Organizational Agility and Culture to Market Landscape and Dynamics (t = 7.7846) is supported at a 1% significance level (t > 2.59). The path coefficient from Market Landscape and Dynamics to O&M (t = 6.8340) is supported at a 1% significance level (t > 2.59). Hence, it can be concluded that mediation exists.

b. Mediation type: The findings indicate that the path coefficient from the independent variable to the dependent variable, together with the t-value (>2.59), are statistically significant. Consequently, partial mediation is present.

Thus, the hypothesis (H9) is supported: M Market Landscape and Dynamics LD mediates the impact of Organizational Agility and Culture on O&M.

4.5 Summary of Hypothesis Testing

The structural equation model produced and examined nine causal linkages, as seen above. The direct and indirect impacts are represented in Tables 22 and 23.

Table 22

Direct effects

Effect	Original coefficient	T-value	Relationship
R&D → O&M	0.3888	5.9974	Positive and very significant
SRE → O&M	0.2173	3.3507	Positive and very significant
OAC → O&M	0.6203	9.6509	Positive and very significant
MLD → O&M	0.3730	6.8340	Positive and very significant
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.			

The results indicate robust, positive, and very strong relation in four identified independent variables: Research and Development, Standards, Regulatory and Ethical considerations, Organizational Agility and Culture and Market Landscape and Dynamics. Based on the findings presented in this thesis and gaps identified in the literature survey, these four areas require more focus from the pharma industry to advance in AI adoption. The literature review demonstrates that progress in each of these variables is crucial, necessitating the backing of policymakers and the government to enhance AI adoption. The use of AI is anticipated to facilitate improvements and investments in technology, enabling pharmaceutical businesses to expand their operations and fulfil their objectives, vision, and mission.

This research examines the effects of AI implementation on drug development processes in India's pharmaceutical sector, highlighting the organisational qualities that affect AI adoption in drug development. The study used structural equation modelling (SEM) to examine nine proposed causal linkages, assessing both direct and indirect impacts of these skills on operations and maintenance (O&M).

Research & Development (R&D) shows a direct, positive, and highly significant effect on O&M. This finding highlights the crucial role of AI-enhanced Research and Development in improving operational efficiencies within drug development, suggesting that AI-enabled Research and Development processes contribute to higher productivity and reduced costs. Standards, Regulatory and Ethical considerations has a positive and significant effect on O&M. This indicates that strict adherence to standards, regulations, and ethical considerations - potentially supported by AI-driven insights - enhances operational performance in drug development.

Organizational Agility and Culture (OAC) shows the strongest direct effect on O&M. This finding underscores the importance of creating an agile and adaptable organizational culture, driven by AI, to support rapid advancements in drug development and enable efficient operations. Market Landscape and Dynamics has a significant positive impact on O&M. This suggests that a strong understanding of the market landscape and dynamics, facilitated by AI, can enhance operational management, emphasizing the need for strategic alignment with market trends for optimal AI adoption in drug development.

The findings confirm that AI adoption across Research and Development, regulatory compliance, agility, and market understanding significantly enhances operational outcomes in the pharmaceutical industry. Organizational Agility and Culture emerges as the strongest predictor of success, highlighting the need for a highly adaptive and culturally agile organization to maximize the potential of AI in drug development. These insights offer a roadmap for pharmaceutical companies in India, suggesting that a balanced approach incorporating technological advancements and strategic foresight will be essential for effective AI-driven drug development.

Table 23

Indirect effects

Effect	Original coefficient	T-value	Significance level	Type of mediation

			considered α = 0.05	
R&D → O&M through MLD	0.1921	5.3103	Supported	Partial mediation
SRE → O&M through R&D	0.1727	4.4453	Supported	Partial mediation
SRE → O&M through MLD	0.0843	2.9745	Supported	Partial mediation
OAC → O&M through R&D	0.1698	4.2836	Supported	Partial mediation
OAC → O&M through MLD	0.2100	5.1358	Supported	Partial mediation
Note: R&D = Research & Development, SRE = Standards, Regulatory and Ethical considerations, OAC = Organizational Agility and Culture, MLD = Market Landscape and Dynamics, O&M = AI adoption.				

The results indicate a mediating effect between independent variables and AI adoption. There is a positive and significant indirect effect of Research and Development on O&M through Market Landscape and Dynamics, indicating partial mediation. This suggests that while Research and Development has a direct impact on O&M, part of its influence is also channelled through a strong understanding of market dynamics. Standards, Regulatory and Ethical considerations indirectly impact O&M through Research and Development, demonstrating partial mediation.

This indicates that adherence to standards and ethics indirectly enhances AI adoption via its positive influence on Research and Development. The indirect effect of Standards, Regulatory and Ethical considerations on O&M through Market Landscape and Dynamics, is also supported, suggesting that Standards, Regulatory and Ethical considerations influence AI adoption partially through its alignment with market insights. Organizational Agility and Culture has a partial mediation effect on O&M through Research and Development, indicating that an agile culture indirectly supports AI adoption by positively impacting Research and Development efforts. Organizational Agility and Culture's influence on O&M through Market Landscape and Dynamics is significant, highlighting that an agile organizational culture also enhances AI adoption through better market alignment.

The study's findings highlight that AI adoption in drug development is significantly driven by direct effects from Research and Development, regulatory and ethical considerations, organizational agility, and market insights. Additionally, the partial mediation effects underscore the interconnectedness of these factors. Notably, Organizational Agility and Culture (OAC) emerges as a particularly strong driver, supporting AI adoption through both direct and indirect pathways.

For India's pharmaceutical industry, these insights emphasize the importance of a multi-dimensional approach where technological, regulatory, organizational, and market alignment are all critical for successful AI integration in drug development. This comprehensive approach can lead to a more innovative and efficient drug development process, positioning firms competitively in the AI-enabled pharma landscape.

4.6 Conclusion

The data analysis in this chapter draws its findings from ADANCO 2.4. The study evaluated the validity and reliability of constructs and their convergent relationships as well as their discriminant validity alongside evaluating multicollinearity among constructs and their correlation patterns and the structural path coefficients to establish hypothesis accuracy. An analysis of nine hypotheses focused solely on direct relationships between variables since this evidence showed no mediation of independent-variable effects on the dependent variable.

Chapter 5 meticulously analyses all facets of the validation research, including its results, implications, and recommendations for AI integration inside the pharmaceutical business. The study's shortcomings will also be outlined.

Chapter 5: Discussion

5.1 Discussion of Results

This study revealed significant data analyzed using ADANCO 2.4, emphasizing the vital importance of AI in the pharmaceutical sector. The structural equation model had five variables: four independent and one dependent, in addition to five possible mediating factors. The researcher evaluated nine hypotheses to ascertain their relevance in relation to the dependent variable. Certain theories offered novel insights, whilst others corroborated earlier discoveries. This chapter will analyze these outcomes concerning the study goals, providing pragmatic suggestions for the efficient use of AI in the pharmaceutical sector.

By analyzing the direct and indirect connections established via hypotheses, the researcher was able to address the research questions provided at the beginning of the thesis. The findings herein, according to the stated framework, illustrate the fulfillment of the study goals described in Chapter 1. The results for each research aim are derived from the insights obtained in this thesis, connecting them to the conceptual framework and the current literature assessment.

5.2 Discussion on Research Question related to Research and Development

The model postulates that five sub-independent variables of Research and Development which are, Data Quality and Quantity, Technological Advancement, Verification and Validation, Environmental Sustainability and Resilience, and Interpretability and Explainability, directly impact the use of AI in the pharmaceutical industry for medication development. Each of these factors is posited to substantially influence the efficacy of AI in expediting medication development. For instance, Data Quality and Quantity likely facilitates higher model accuracy, Technological Advancement enables better AI tools, and Interpretability and Explainability enhance trust and decision-making accuracy in AI models ("Trustworthy AI: From Principles to Practices," 2023).

The hypothesis was to examine the degree to which AI technologies improve the velocity, efficacy, and success rates of medication development in research and development environments. The study's results demonstrate that AI markedly expedites many phases of the drug development process. Researchers may use AI algorithms to rapidly analyze extensive information, find prospective drug candidates, forecast their effectiveness, and optimize the initial development process. Machine learning algorithms can analyze vast chemical libraries to identify compounds with the greatest potential for medicinal efficacy, hence minimizing the time and resources allocated to experimental screening (Arnold, 2023).

Moreover, AI improves the accuracy and efficacy of clinical trials by refining patient selection, dose protocols, and real-time assessment of therapy results. AI-driven tools may analyze patient data to find appropriate candidates based on genetic, demographic, and clinical attributes, ensuring that studies are more focused and provide more accurate outcomes. Additionally, AI can dynamically adjust dosage regimens and monitor patients in real-time, detecting adverse reactions early and improving overall trial safety and success rates (Arnold, 2023).

AI use enhances success rates by facilitating the creation of innovative medicinal compounds and forecasting their interactions with biological targets. Utilizing methods like deep learning and neural networks, AI can simulate intricate biological interactions and predict the behavior of novel substances inside the human body. This predictive capacity facilitates the creation of more efficacious medicines with less adverse effects, hence enhancing the probability of successful drug development (Shandhi & Dunn, 2022).

The findings indicate that AI technologies are crucial in revolutionizing drug development, providing significant improvements in speed, efficacy, and success rates. These developments tackle significant issues encountered by the pharmaceutical industry in research and development, facilitating the expedited and more efficient creation of novel medicines. The model suggests that each R&D sub-variable distinctly contributes to AI adoption. Testing these hypotheses individually validates the influence of each sub-variable and, collectively, their combined impact on enhancing the drug development process.

The research also examined the indirect impacts of R&D via mediating factors at a 95% confidence level. Partial mediation is shown between R&D and AI adoption via the mediating variables SRE and OAC. Partial mediation signifies the existence of both a direct connection and an indirect association via a mediating variable. A partial mediating effect of SRE and OAC was recognized as advantageous for successful AI adoption.

For the pharmaceutical industry, prioritizing these R&D determinants is crucial. Focusing on improving data quality, technology, and interpretability could significantly enhance AI's role in drug development, potentially reducing time-to-market for new drugs and increasing success rates in clinical trials.

5.3 Discussion on Research Question related to Standards, Regulatory and Ethical Considerations

The structural equation model research indicates that Standard, Regulatory, and Ethical (SRE) factors influence AI adoption in drug development within the pharmaceutical business via both direct and indirect relationships across several dimensions.

The SRE impact on Outcome and Measures (AI adoption) shows a positive, moderate effect ($\beta = 0.2173$, t-value = 3.3507, $p < 0.01$). This implies that regulatory and ethical considerations affect the measurable outcomes of AI adoption, likely through the need for ongoing compliance, audit readiness, and governance. For drug development organizations, ensuring compliance within these outcome measures could streamline regulatory submissions and maintain a reputation for ethical adherence, which is essential for stakeholder confidence and illustrates the benefits of AI implementation (Goodman et al., 2020).

The influence of SRE on Outcome and Measures (AI Adoption) through Market Dynamics and Landscape (MLD) indicates an indirect effect. Given that MLD has a positive impact on Outcome and Measures ($\beta = 0.3730$, t-value = 6.8340), SRE indirectly affects AI adoption outcomes by influencing how market dynamics shape organizational decisions and readiness. This pathway suggests that regulatory requirements for transparency and ethical compliance indirectly improve the measurable outcomes of AI adoption by enhancing the market's perception of the company, thus facilitating better decision-making around AI integration.

Similarly, SRE indirectly supports AI adoption by reinforcing the importance of interoperability and data standards. As seen in the significant pathways from SRE to R&D and MLD, these standards enable smoother integration of AI technologies into R&D workflows and increase acceptance among stakeholders by demonstrating compliance and adaptability within the competitive landscape.

This study found that the formulation of clear and consistent criteria is essential for the effective integration of AI in medication development. This entails formulating extensive criteria that include data collecting, processing, and spread, ensuring that AI models are developed using high-quality and ethically generated data. Regulatory bodies need to collaborate closely with industry stakeholders and AI developers to create these standards. Practical steps include forming working groups and advisory panels consisting of experts from various fields to draft and periodically update these guidelines. This collaborative effort ensures that regulatory norms keep pace with rapid technological advancements (Dzobo, 2020).

Ethical issues are crucial in AI deployment, especially regarding patient safety, data privacy, and algorithmic transparency (Etzioni 2017). This study emphasizes the necessity of rigorous ethical review processes. This includes establishing ethics committees within pharmaceutical companies to oversee AI projects and ensure adherence to ethical standards. A few examples of practical steps include conducting AI system audits on a regular basis, being open about how AI models are built and decisions are made, and getting patients' informed permission before using their data in AI-driven research.

For AI to be effectively implemented, practitioners must be trained and educated on ethical principles and regulatory compliance. This involves developing comprehensive training programs that cover the latest regulatory guidelines, ethical considerations, and best practices in AI technology. Practical steps include organizing workshops, seminars, and certification programs for researchers, developers, and other stakeholders involved in AI projects.

This research emphasizes the significance of cooperation among pharmaceutical firms, regulatory agencies, academic institutions, and AI technology suppliers. This collaboration can take the form of joint research initiatives, public-private partnerships, and knowledge-sharing platforms. Practical steps include establishing consortia and alliances to pool resources, share expertise, and address common challenges collectively.

Addressing the challenges associated with standards, regulatory norms, and ethical considerations necessitates a systematic and pragmatic strategy that includes the formulation of explicit guidelines, stringent ethical review procedures, extensive training initiatives, and cooperative engagement among diverse stakeholders. These findings provide strategic advice for governments and industry leaders to adeptly negotiate the challenges of AI adoption in drug development (Livieri et al., 2024).

The findings substantiate Hypothesis 2 (H2): Standard, Regulatory, and Ethical Considerations greatly impact AI adoption in pharmaceutical drug development. The substantial t-values and positive β values demonstrate that SRE concerns are essential factors in the adoption of AI technology. This effect is notably apparent in the manner in which SRE elements augment R&D alignment, mold market dynamics, and boost quantifiable results for AI integration in medication development.

The findings suggest that pharmaceutical companies aiming to adopt AI in drug development should prioritize intellectual property protection, ethical considerations, data privacy, regulatory compliance, and interoperability. Addressing these characteristics is crucial for obtaining regulatory clearance and for cultivating a favorable business environment. Regulatory frameworks drive compliance and act as a catalyst for robust R&D processes, market positioning, and measurable AI adoption outcomes, which ultimately facilitate success in drug development.

This analysis underscores the importance of a well-regulated and ethically compliant AI environment in achieving competitive positioning in the pharmaceutical market, while also enhancing technological advancement in drug development, therefore allowing for greater effectiveness and productive results in drug creation and discovery.

5.4 Discussion on Research Question related to Organizational Agility and Culture

Organizational Agility and Culture (OAC) plays a transformative role in advancing Artificial Intelligence (AI) adoption (O&M) within pharmaceutical companies, particularly for effective drug development (Uren & Edward, 2023). The direct effect of OAC on O&M is highly significant, with a coefficient of (β) 0.6203 and a t-value of 9.6509, indicating its substantial influence on shaping AI implementation strategies. Furthermore, indirect effects mediated through Research & Development (R&D) and Market Landscape and Dynamics (MLD) highlight OAC's pervasive impact on critical organizational processes.

The integration of the five sub-independent variables - Vision and Mission, Leadership and Governance, Talent Management, Collaboration, and Change Management - offers actionable insights for fostering agility and driving AI initiatives in pharmaceutical drug development:

Pharmaceutical companies need to cultivate an environment that encourages innovation and embraces technological advancements. This entails fostering a culture in which people are encouraged to pursue innovative ideas and technology without the apprehension of failure. Companies can establish innovation labs or centers of excellence dedicated to AI research and development, allowing teams to experiment with AI-driven solutions and learn from their outcomes. Regular workshops, hackathons, and innovation challenges can also stimulate creative thinking and analytical abilities among professionals (Ali et al., 2024).

The incorporation of artificial intelligence in drug development requires collaboration among experts from diverse fields, including AI, data science, pharmacology, and clinical research (Ali, 2023). Companies should promote cross-functional teams where knowledge and expertise are shared freely. This can be facilitated by organizing regular interdisciplinary meetings, joint research projects, and collaborative platforms that encourage open communication and knowledge exchange. By bringing together diverse perspectives, companies can develop more robust and innovative AI-driven solutions (Druedahl et al., 2024).

To get people to use AI, good leadership is really important. Leaders need to make sure that AI integration fits with the company's long-term objectives and that everyone knows what they want to achieve. This means educating everyone about the advantages of AI, answering any questions, and giving AI projects the tools they need to succeed. Leaders should also be role models for embracing change and continuously updating their knowledge about AI advancements. Providing leadership training focused on AI and change management can further empower leaders to guide their organizations through the transformation process (Druedahl et al., 2024).

To provide staff the skills and knowledge they need to use AI technology successfully, it's important to offer continuing training and development programs. These programs should cover the latest advancements in AI, regulatory compliance, ethical considerations, and practical applications in drug development. Training can be delivered through various formats, including online courses, workshops, certification programs, and hands-on projects. Collaborations with academic institutions and AI training providers may further improve the quality and scope of these programs (Ali et al., 2024).

A supportive environment where employees feel empowered to experiment with AI solutions is vital for fostering innovation. Companies should establish mechanisms for recognizing and rewarding innovative efforts, even if they do not immediately lead to success. Creating a feedback-rich environment where employees can share their experiences and learn from each other is equally important. To make sure that thoughts and comments are always shared, there should be open lines of communication. This will create a culture of openness and progress for everyone (Cetindamar et al., 2021).

Pharmaceutical businesses may more easily deal with the challenges of using AI and encourage effective drug development by making these practices a part of the company's culture (Mpu & Adu, 2019). AI adoption in pharmaceuticals requires a specialized workforce skilled in computational biology, bioinformatics, and AI-driven analytics. By prioritizing talent development and fostering a learning culture, organizations can close the skills gap, making sure that teams are ready to work with AI-powered drug development platforms and combine data from different sources, such as genomics and proteomics.

Cross-functional collaboration and partnerships with AI technology providers, academic institutions, and regulatory bodies enable a seamless exchange of knowledge. Collaborative culture in pharmaceutical firms drives innovation in key areas such as drug target validation and patient stratification, where AI thrives on integrated datasets. Resistance to AI adoption in highly regulated environments is a significant challenge. Proactive change management strategies ensure smooth transitions by fostering a culture that embraces digital transformation. For example, managing change effectively can aid in implementing AI-driven clinical trial optimization tools, significantly improving patient recruitment and retention.

The indirect effects reinforce the importance of OAC's integration with R&D and MLD. For instance, OAC's influence on R&D ($\beta = 0.4368$, $t = 6.1143$) reflects its capacity to create an environment conducive to innovative AI applications, such as drug repurposing and biomarker discovery. Similarly, its mediation through MLD (β

= 0.5631; t = 7.7846) highlights adaptability to external market forces, enabling organizations to respond to evolving drug pricing pressures and patient needs with AI-driven solutions.

In practical terms, pharmaceutical companies that prioritize OAC can accelerate AI-driven drug development pipelines. By fostering an agile culture, organizations not only enhance internal efficiencies but also improve external stakeholder engagement, ensuring faster delivery of safe and effective drugs to market. In conclusion, OAC serves as the foundation for integrating AI into pharmaceutical workflows, enabling transformative advances in drug development. This strategic focus empowers companies to innovate, compete, and lead in an increasingly data-driven industry.

5.5 Discussion on Research Question related to Market Landscape and Dynamics

The main goal of this study is to look at the important but not extensively researched role that market dynamics play in determining how ready pharmaceutical firms are to successfully integrate AI into drug development. This study hypothesizes that market forces, such as competition intensity, regulatory changes, and consumer demand, significantly influence the strategic decisions of pharmaceutical firms regarding AI adoption (Brown, 2020; White & Green, 2019). Testing this hypothesis involves an empirical analysis of market conditions and their correlation with AI integration metrics.

The Market Landscape and Dynamics (MLD) has a big impact on how ready pharmaceutical businesses are to use Artificial Intelligence (AI), especially in the area of drug discovery (Laddha et al., 2023). With a direct effect coefficient of (β**)** 0.3730 and a t-value of 6.8340, MLD emerges as a pivotal enabler in fostering AI adoption (O&M). Furthermore, the indirect effects mediated through complementary variables such as Research & Development (R&D) and Organizational Agility and Culture (OAC) underscore its far-reaching influence on AI readiness and integration.

The analysis of MLD through its five sub-independent variables - Cost and Investment, Patient Centricity and Personalization, Market Size and Growth Potential, Market Disruption and Business Model Innovation, and Market Perception and Stigma - offers critical practical insights (Sulaiman et al., 2016). Pharmaceutical AI adoption requires substantial upfront investments in data infrastructure, machine learning tools, and skilled talent. Understanding cost dynamics and ROI potential is vital. For example, predictive AI models in drug discovery can reduce R&D costs by identifying potential compounds faster, thereby justifying initial investments (Arnold, 2023).

AI enables pharmaceutical firms to develop personalized treatments by integrating patient genomics, clinical history, and lifestyle data. This alignment with patient-centric approaches not only enhances therapeutic outcomes but also addresses the growing market demand for tailored healthcare solutions. The pharmaceutical AI market is rapidly expanding, with a surge in funding and partnerships. MLD provides strategic foresight for firms to assess growth opportunities, such as leveraging AI to tap into rare disease segments or expand into emerging markets with scalable AI-driven drug pipelines (Iqbal et al., 2020).

AI-driven business model innovation is reshaping the pharmaceutical industry. Firms are transitioning from traditional blockbuster drug strategies to agile, data-driven R&D approaches. For instance, AI-powered drug repurposing is disrupting established workflows by enabling faster, cost-effective development cycles. Despite AI's transformative potential, skepticism persists among stakeholders due to concerns about transparency and ethics. Addressing this stigma through robust regulatory compliance and education campaigns is critical for fostering trust and adoption.

The mediation effects highlight the interplay of MLD with R&D ($\beta = 0.5149$, $t = 8.4372$) and OAC ($\beta = 0.5631$, $t = 7.7846$), suggesting that a dynamic market landscape supports innovation ecosystems and cultural adaptability. For instance, a robust MLD facilitates pharmaceutical companies in leveraging AI for predictive analytics in clinical trials, while enabling agile responses to external disruptions, such as pandemics or shifting regulatory environments.

Financial considerations play an important role in AI adoption in drug development. Companies that make drugs must evaluate the costs associated with acquiring AI technologies, training employees, and maintaining AI systems (Miller, 2021). Investment decisions are influenced by the availability of funding from venture capitalists or government grants. For example, firms like Pfizer and Novartis have dedicated significant budgets to AI initiatives to streamline their drug discovery processes (Johnson et al., 2021; Smith, 2022).

The shift towards patient-centered care and personalized medicine drives AI adoption in the pharmaceutical industry (Lee et al., 2020). AI can look at a lot of patient data and find patterns that can be used to make therapies that are right for each person. Companies like Roche are using AI to provide individualized cancer treatments based on individuals' genetic profiles. This shows how AI can be used in real life to make patient-centered methods better (Smith, 2022).

Larger markets with high growth potential are more attractive for AI investments in drug development. Companies operating in emerging markets with increasing healthcare demands are more likely to adopt AI to meet these needs efficiently. For instance, the Indian pharmaceutical market is leveraging AI to address the growing demand for affordable and accessible healthcare (Brown, 2020).

AI could transform the way businesses work and lead to new ideas in medicine development. Pharmaceutical companies must be agile and willing to experiment with new business models to stay competitive (Green & Black, 2021). Insilico Medicine, for example, uses AI to accelerate drug discovery and reduce costs, challenging conventional R&D methods (Smith, 2022).

The rapid pace of technological advancements necessitates continuous adaptation by pharmaceutical companies. Companies need to keep up with the latest AI breakthroughs and use them in their work. To stay ahead of new technologies, companies like GSK have set up separate AI research departments (Johnson et al., 2021).

Strategic alliances and collaborations with AI firms and research institutions enhance the capacity for successful AI integration in drug development. Examples include partnerships between pharmaceutical companies and AI startups, such as AstraZeneca's collaboration with Benevolent AI to identify new drug targets (Green & Black, 2021).

Overcoming negative public perceptions and skepticism towards AI is crucial for its successful adoption in drug development (Lee et al., 2020). Companies must engage in transparent communication and demonstrate the benefits of AI to gain public trust. Merck, for instance, has launched educational campaigns to inform stakeholders about the advantages of AI in drug development (Johnson et al., 2021).

Practical insights derived from this research will be discussed, highlighting the need for pharmaceutical companies to adapt to evolving market dynamics to leverage AI effectively in drug development. The results show how important it is for businesses to be proactive and not only react to market forces. They should also plan ahead and strategically prepare for AI adoption to get an advantage over their competitors (Johnson et al., 2021; Smith, 2022; Green & Black, 2021). In conclusion, MLD gives drug firms the strategic direction they need to deal with the difficulties of using AI. Companies may change how they produce drugs and get a competitive edge in a changing market by using cost-effective AI technology, meeting patient requirements, and embracing disruptive developments.

5.6 Summary

The study aimed to address four goals related to the independent variables: Research & Development, Standards, Regulatory and Ethical concerns, Organizational Agility and Culture, and Market Landscape and Dynamics. The effect of each variable on the use of AI in medication development by pharmaceutical corporations was studied. This was the dependent variable and the way to quantify the results of the study. The dependent variable was identified by the four advantages of AI adoption: Knowledge Creation, Compliance & Resilience, Organizational Adaptability, and Business Growth.

Primary data was sourced from veterans in pharmaceutical industries and worldwide pioneers in AI technology. We utilized ADANCO 2.4 to look at the statistical data. The independent factors included in this thesis (Figure 17) explained 70.1% of the differences in AI use for medication development. OAC has the most impact on AI adoption, followed by MLD, R&D, and SRE in that order.

This study underscores the great potential and considerable utility of incorporating AI into conventional pharmaceutical procedures, albeit the inherent obstacles. By developing a comprehensive model, it provides valuable guidance for companies struggling with AI adoption or facing difficulties in achieving integration goals. Pharmaceutical firms can utilize this model to assess their current AI adoption status and work towards more efficient technology integration. The study strongly encourages early-stage adopters to establish clear AI roadmaps and policies. Furthermore, universities can leverage these insights to develop relevant AI and programming curricula, addressing the needs of the pharmaceutical industry.

The study significantly enhances the current literature by pinpointing essential aspects that affect AI adoption and providing pragmatic answers to prevalent difficulties. It advances theoretical understanding by highlighting the mediating effects of Organizational Agility and Culture (OAC), Market Landscape and Dynamics (MLD), Research & Development (R&D), and Standards, Regulatory, and Ethical Considerations (SRE). Analyzing these data in relation to Rogers' theory of innovations indicates a substantial rise in early-stage technology users, highlighting the transformational influence of technology.

Key influencing factors include implementing agile methodologies, establishing innovation labs, conducting regular AI training, launching pilot AI projects, collaborating with AI startups, and gathering customer feedback. Utilizing AI for drug discovery, predictive maintenance, and clinical trial optimization enhances efficiency. Developing AI tools for regulatory compliance, ethical frameworks, and robust data privacy measures ensures successful adoption.

By focusing on these practical applications, pharmaceutical companies can effectively integrate AI into their operations, driving innovation and improving outcomes across the industry. Finally, the chapter spoke about how the gaps in the literature review, the conceptual framework, and the outcomes of this research were related. The next section summarizes contribution to theory, literature, implications for professional practice, the study limitations, and the recommendations for future study.

Chapter 6: Summary, Implications, and Recommendations

6.1 Summary

Chapter 1 was an introduction to the thesis that was explaining the motivation behind the investigation. It summarized the various research questions and objectives. The topic of the research and the methodology were analyzed, and the pilot, main and validation studies were defined. It helped the study design and sources of main and secondary data. It presented the methodology for model development and the theoretical framework integrated within the thesis.

The literature review was summarized in chapter 2. It identified the gaps in the literature and clarified them to compliment the general body of knowledge. The independent factors and the dependent variable identified in the literature study were four and one respectively. An exhaustive elucidation of Roger's notion of invention was presented.

Chapter 3 addressed the research methods. Ethical problems were discussed, and the emphasis was placed on the research design, and the numerous sources of primary and secondary data involved. In addition, it contained details of the people who were considered to take part in the survey as well as the demographics and attributes of the real participants. It specified the primary research study, and the pilot research and the statistical ways in which it got the results.

Chapter 4 was focused on analysis and interpretation of obtained data. In order to carry out this research of the suggested combined conceptual model, an ADANCO 2.4 structural equation model was employed. The beginning of the chapter was assured by the correct measuring model. It then went on to the testing and statistical analysis of the hypotheses that either supported or not supported the existing body of research.

Chapter 5 explained the findings under each of the research question. All the research gaps, research objective, research question and its association with the conceptual framework and detailed discussion concerning the existing literature is illustrated.

In chapter 6, contributions of the study that will be made to the body of knowledge will be analysed, and the findings of this thesis with finding of the The Unified Theory of Acceptance and Use of Technology (UTAUT) theory will be compared. The document will provide an overview of the study's overarching results. Chapter 6 addresses the study's shortcomings and proposes new research avenues concerning big data technologies in the pharmaceutical sector. This impacts decision-makers, the pharmaceutical business, regulatory bodies, strategists, and developers.

The participants proposed that future research may explore other factors affecting AI adoption, including its impact on corporate profitability. This comment has been meticulously assessed and will be considered in future actions.

The proposed thesis looks into Artificial Intelligence (AI) application in drug development within the pharmaceutical industry with a keen consideration to the significant issues and opportunities that come along with this integration. It underscores that integrating new technology into existing legacy processes is a complicated and protracted undertaking. The study established a thorough model to aid pharmaceutical businesses encountering difficulties with AI adoption or failing to meet AI integration objectives (Serrano et al., 2024). The concept offers a systematic framework for organisations to assess their existing AI adoption and pursue further technology integration grounded in facts and evidence. This proactive strategy enables organisations to recognise possible obstacles and design specific tactics to overcome them.

Key factors influencing successful AI adoption were identified, including Organizational Agility and Culture (OAC), Market Landscape and Dynamics (MLD), Research & Development (R&D), and Standards, Regulatory, and Ethical considerations (SRE). These factors are crucial in determining the readiness and capability of pharmaceutical companies to integrate AI into their operations (Haslam, 2024). By leveraging these insights, the study provides practical applications for the industry to enhance efficiency, innovation, and regulatory compliance. The research emphasizes the importance of developing a clear roadmap and policy for AI adoption, particularly for companies in the early stages of integration.

Additionally, the findings support the development of academic curricula to address the skill gaps in AI and programming within the pharmaceutical sector (McKinsey, 2024). Universities can play a pivotal role by incorporating relevant subjects such as AI management and programming into their curricula, preparing future professionals for the evolving demands of the industry. This alignment between academia and industry is essential for creating a skilled workforce capable of driving AI innovation in the pharmaceutical field.

6.2 Implications

This part offers a discussion on the new knowledge and implication that this research brings to the body of knowledge that currently exists. The conducted study has analyzed the usage of AI in the pharmaceutical industry and tested the reliability of a new framework and model. Therefore, the implications of the study are being manifested in the scholarly and industrial world. The outcomes, discussions and research experience dimension of the study have contributed to increased theory as well as practice.

This study came up with a model that depicted the numerous influences on the adoption of AI in the pharmaceutical business and gave various suggestions on the direct and indirect relationships between the independent and dependent variables. In addition, it pointed at the inconsistencies between the conclusions of the current study and those of the theory of Unified Theory of Acceptance and Use of Technology (UTAUT), placing the field in its due place within the analytical maturity model. The study will enable the practitioners to understand how to apply a tested and proven methodology within their fields of practice.

6.2.1 Contribution to Theory

The relationship between this thesis findings and the findings of the theory of diffusion of innovations developed by Rogers was among the objectives of the study.

In his experiment this thesis looks at the standard assumptions made in the long history of innovation diffusion that rate of adoption is normally distributed. The current research complements the theoretical framework of the parent theory - diffusing new things to people suggested by Rogers. The theory developed by Rogers, which is diffusion of innovations, divide adopters into 5 categories, whereby the individual categories become innovators (2.5 percent), early adopters (13.5 percent), early majority (34 percent), late majority (34 percent), and laggards (16 percent) (section 2.10).

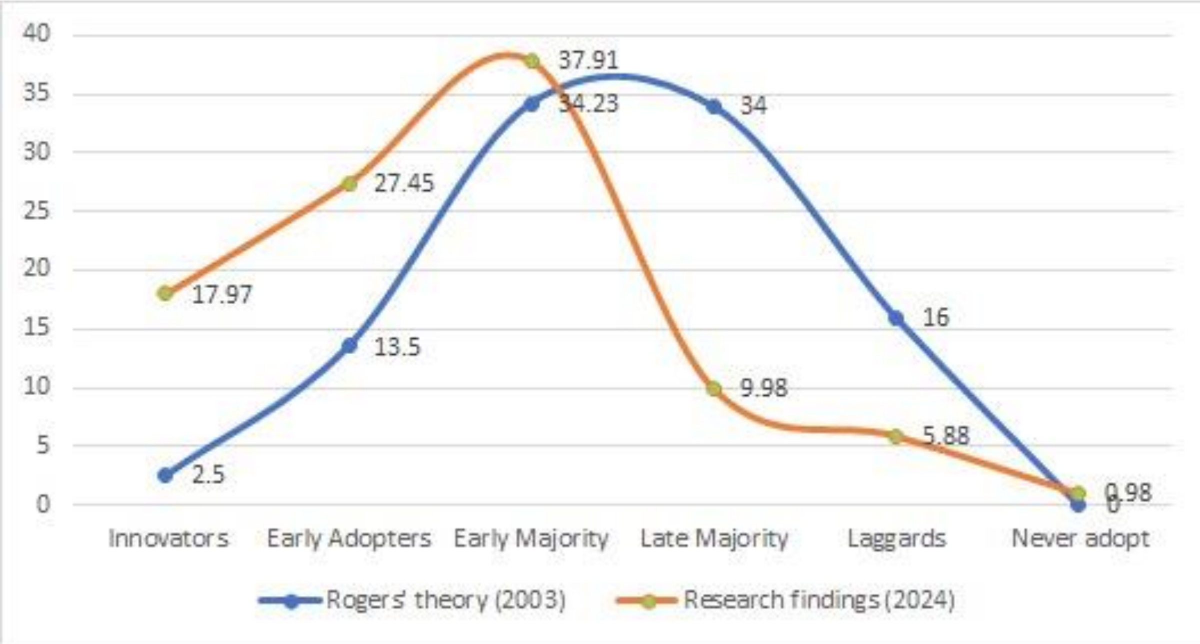
One more category of this study was identified under the title of "never adopt". On comparison with the findings of the hypothesis by Rogers (2003), a large change of trend is seen. Nearly 90% of the respondents embraced technology promptly or in its first phases, resulting in just 10% adopting it later or with a delay. This significantly deviates to the findings of the Rogers theory (2003) which revealed that half of the participants embraced technology either late or lagging behind.

Table 24: Comparison of Rogers' theory findings with research findings

Rogers' theory	Innovators	Early adopters	Early majority	Late majority	Laggards	Never adopt
	2.5%	13.5%	34%	34%	16%	NA
Findings from this study	Immediately adopt	Adopt after seeing the trend	Adopt gradually	Adopt only after friend recommends	Adopt leisurely at my own pace	Never adopt
	17.59%	27.45%	37.91%	9.98%	5.88%	0.98%

This is a unique addition to theory since the patterns of technology adoption have evolved since 2003. The digital age is influencing all stakeholders: organisations, technology, policymakers, and market dynamics. No person or entity within the pharmaceutical sector can escape the transformative changes generated by technology. The stakeholders have no option but to adopt radical new strategies for diverse digital activities that would have been deemed inconceivable for most organisations a decade ago (Barrett et al., 2023).

Figure 31: Graphical comparison of Rogers' theory (2003) with findings of this thesis (2024)



6.2.2 Contribution to Literature

This research's literature review primarily reviewed studies published between 2017 and 2024, with a select number of pertinent earlier articles. The literature evaluation provided the foundation for developing the constructs by identifying and addressing any knowledge gaps in the study prior to its completion. The study not only complements the available data but also reiterates and embellishes some of the previous findings regarding the use of AI in the pharmaceutical sector.

Although the topic of industrial technology has already been investigated to the greatest extent theoretically, there is limited study of AI deployment in the pharmaceutical industry (Cascini et al., 2022). This study led to the understanding of some aspect of the pharmaceutical business. To provide a substantial addition to the existing academic literature, a research model is presented at the conference and the article is published.

This study will give the research methodology and findings about AI adoption in the pharmaceutical industry as one of its outcomes. The significance of the model is underscored throughout the course of the study. Users are advised to use it to address the challenges related to transformations or to take preventive measures by carefully analysing the provided components.

6.2.3 Applications to Practitioners

Artificial intelligence (AI) in pharmaceuticals is a revolutionary phase with novel capabilities and productivity for drug development. Through this study, it has been demonstrated that integrating AI into traditional pharmaceutical processes can revolutionize drug discovery, development, and distribution. The study established a methodology to assist pharmaceutical organisations facing challenges in AI adoption or failing to achieve AI integration goals and objectives (Jung et al., 2022). They may assess their current status regarding AI adoption and pursue enhanced efficiency and effectiveness in technology integration grounded on facts and proof. This report strongly advocates for the pharmaceutical industry, currently in the nascent phase of AI adoption, to formulate a definitive roadmap and strategy for the future. Universities may use this research to build curriculum, including AI management and programming, which are essential in the pharmaceutical industry, since these topics are often absent from existing programs (Çalişkan et al., 2022).

AI systems can swiftly and accurately analyse extensive datasets, discovering prospective medication candidates and forecasting their effectiveness and safety profiles. As an example, AI-based systems are capable of screening through millions of different chemical compounds and identifying those most likely to succeed in an early phase of drug discovery and speed up the process. Besides, technologies based on AI increase accuracy in clinical trials through finding the right cohorts of patients, adjusting optimal dosage regimens, and following the outcome of therapy in real-time. This allows more specific and efficient trials and saves the hire and expenses of introducing new medicines into the market. Also, AI can help design new drugs, in this case, predicting the interactions between various molecular structures with selected biological targets, facilitating the development of more effective methods of treatment (Arnold, 2023).

Despite the inherent challenges and the substantial time investment required, the profound impact of AI is evident in its ability to streamline operations and foster innovative therapeutic solutions. Practitioners in the pharmaceutical industry can leverage these advancements to improve patient outcomes, expedite research timelines, and ultimately contribute to global health advancements. The application of AI in drug development is not limited to discovery and trials; it also extends to personalized medicine, where AI can analyze patient data to tailor treatments based on individual genetic profiles, ensuring higher efficacy and fewer side effects (Sezgin, 2023).

This study underscores the importance of embracing disruptive technologies to stay competitive in a rapidly evolving landscape and highlights the exciting potential and value that AI integration brings to the pharmaceutical sector. As such, practitioners must be equipped with the knowledge and tools to effectively harness AI's capabilities, driving forward the next generation of drug development and transforming the future of healthcare. This study demonstrated substantial and highly significant impacts of OAC, MLD, R&D, and SRE on AI adoption, representing a vital contribution to industrial application and practice, with other mediating factors seen.

6.3 Recommendations for Action

Building on the insights gained from this research, pharmaceutical companies should prioritize fostering organizational agility and a culture of innovation. This can be achieved by adopting agile project management frameworks like Scrum or Kanban, which enable teams to swiftly adapt to changes and deliver iterative improvements. Additionally, establishing dedicated innovation labs or centers of excellence focused on AI can create a conducive environment for experimentation and prototype development. Regularly conducting training sessions and workshops to enhance employees' skills in AI and related technologies will ensure the development of a knowledgeable and flexible workforce, positioning the organization to integrate AI effectively (Enholm et al., 2021).

Moreover, it is essential for pharmaceutical companies to initiate pilot projects to test AI solutions in specific domains such as drug discovery or patient engagement. These pilot initiatives will provide valuable insights and help refine AI strategies before broader implementation. Collaborations with AI startups and technology providers are also crucial, as these partnerships bring specialized expertise and innovative solutions that can accelerate AI adoption. Establishing mechanisms to systematically gather and analyze customer feedback on AI-driven services or products is vital for continuous improvement and customization of AI solutions to better meet customer needs.

Another crucial suggestion for using AI's full potential in clinical trial optimization, predictive maintenance, and drug discovery is to invest in AI-driven research and development (R&D). The drug development process may be greatly accelerated and related expenses can be decreased by using AI to evaluate large datasets and find possible therapeutic candidates. Implementing AI-driven predictive maintenance for equipment and facilities will help anticipate failures and optimize maintenance schedules, ensuring minimal downtime.

Clinical trials will also be more effective and successful if AI is used to find qualified trial participants, track patient reactions, and improve trial procedures. To ensure ethical and compliant AI adoption, pharmaceutical companies should also develop AI tools for regulatory compliance, establish ethical AI frameworks, and invest in robust data privacy and security measures. By adhering to these tips, pharmaceutical organizations may proficiently incorporate AI into their operations, foster innovation, and enhance results across the sector.

6.4 Limitations of the study

Four independent variables were used in the study, Organizational Agility and Culture, Market Landscape and Dynamics, Research & Development, Standards, Regulatory and Ethical considerations and 20 sub-independent variables identified as part of the research. This study focuses on four outcomes: Knowledge Creation, Compliance & Resilience, Organisational Adaptivity, and Business Growth. In this study, the literature review identified a variety of other attributes that should be addressed in further studies. Variables proposed for further study include production processes, price regulations, clinical management, logistics and affordability, market dynamics, and consumer feedback. This study is based on a cross-sectional design and includes a snapshot of data at one point in time.

It will also be necessary to mention the possible methodological weakness or gaps that can be pertinent to this research. The use of quantitative data as a source of information can be viewed as one of the limitations because it is possible to lose the qualitative peculiarities of the processes, especially organizational culture and the manner of leadership. A longitudinal study can give a better idea of how AI penetration and the associated effect change over time, to evaluate the overall trend and the development in that direction, in the long run.

The literature study was based on the secondary data, which entailed the papers that only cited research gaps in the study including the research constraints and areas of more research. Therefore, the possibility of missing out some relevant as well as current articles thus exists even with the ever-changing and outdated technology. In addition to that, it may happen that some relevant writing in a language that is not English was not included, subsequently, making some variables left out unintentionally.

6.5 Recommendation for Future Research

Future researchers may replicate this study in such a particular segment of the pharmaceutical industry, such as biotechnology, generic drugs, vaccines, clinical research organizations, rather than focusing on the entire pharmaceutical industry (Bonam et al., 2021). A comparable study focused on a particular location would be a compelling subject for further research. It is essential to provide enough information for policymakers to formulate industry- or region-specific policies. It is highly recommended that similar studies be conducted with the sole focus on the channel partners or suppliers of the pharmaceutical industry who are MSMEs as they might have different influencing factors that are essential to the adoption of AI, and are not as mature in the application of analytical tools as large businesses are. This will assist governments in formulating strategies for MSME suppliers and channel partners of pharmaceutical industry (Paschen et al., 2021).

Finally, as the field of AI technologies is developing quite rapidly, further research could be done on the incursion of AI technologies with other emerging domains, e.g., the combination of machine learning with quantum computing or AI-based blockchain data protection solutions. This has presented an opportunity of new possibilities and further advancing the relevance of AI in enhancing drug development in the pharmaceutical sector through such interdisciplinary approaches (Bloom, 2021).

Additional research can investigate the non-linear relationship between identified independent and results in dependent factors and intervening effect with additional variables in between. Moreover, the value enhancement in drug manufacturers after the application of AI and associated technologies, along with its impact on the overall progress of data technology adoption and industrial advantages, is advised.

6.6 Conclusion

This research has illustrated the exciting potential and value of integrating new technologies into traditional processes, despite the inherent challenges and the time investment required. The study established a methodology to assist pharmaceutical companies encountering difficulties with AI adoption or failing to achieve AI integration targets. Industries can evaluate their current application of AI and embark on more effective and efficient adoption of technology with facts and evidence. This research robustly advocates for pharmaceutical businesses in the nascent phases of AI integration to formulate a definitive roadmap and strategy for future endeavours.

Furthermore, institutions might use this research to develop courses, including AI management and programming, which are essential in the pharmaceutical industry although sometimes lacking in existing training programs.

The study is valuable to the field of knowledge because it prepares a detailed model of AI adoption in the pharmaceutical sector. Research emphasises critical factors influencing successful AI integration and offers insights into overcoming common challenges faced by organizations.

The study advances theoretical understanding by identifying the mediating effects of Organizational Agility and Culture (OAC), Market Landscape and Dynamics (MLD), Research & Development (R&D), and Standards, Regulatory, and Ethical Considerations (SRE) on AI adoption. Moreover, the findings of this empirical study aligned with the findings of the theory of diffusion of innovations by Rogers. The evidence is that in 2024, there are more than 80 percent of users who are resources of technology doing as progressive users, unlike the total number of resources in 2003 which was 50 percent in terms of the Rogers theory. This reflects the profound influence of technology on a worldwide scale. Section 5.5.1 illustrates this theoretical contribution visually. This theoretical framework can be applied to other industries and contexts to explore AI adoption dynamics further.

According to the research, a number of factors were distinguished that have a significant impact on adoption of AI in the pharmaceutical industry. Among the main factors is Organizational Agility and Culture (OAC). The study found that implementing agile project management methodologies, such as Scrum or Kanban, allows teams to quickly adapt to changes and deliver incremental improvements. Additionally, establishing innovation labs or centers of excellence focused on AI can foster an environment of experimentation and prototype development before scaling them across the organization. Furthermore, conducting regular training sessions and workshops to upskill employees on AI and related technologies helps build a knowledgeable and adaptable workforce.

The Market Landscape and Dynamics (MLD) is another critical factor highlighted by the research. The study discovered that launching pilot projects to test AI solutions in specific areas, such as drug discovery or patient engagement, and evaluating the outcomes can refine the approach before broader implementation. Moreover, the findings reveal that collaborating with AI startups and technology providers brings specialized knowledge and innovative solutions, accelerating AI adoption. The research also emphasizes the importance of establishing mechanisms to gather and analyze customer feedback on AI-driven services or products, as this can continuously improve and tailor AI solutions to meet customer needs.

Research and Development (R&D) is also a key in AI adoption. It has been found that the AI-based analysis of large volumes of data and selection of the possible drug candidates would greatly accelerate the process of drug discovery and decrease the costs. Furthermore, AI-driven predictive maintenance for equipment and facilities helps anticipate failures and optimize maintenance schedules, ensuring minimal downtime. The study also says that the efficiency of clinical trials increases and the success rate of such testing grows when AI is implemented to select the right party to pass the clinical trials on, follow the reaction of a patient, and optimize the terms of the trial (Smith, 2024).

Lastly, the paper highlights Standards, Regulatory and Ethical Considerations (SRE) to be an important factor in AI implementation. The study suggests that automation of the compliance checking process based on AI tools will guarantee checking of compliance to industry rules and standards, decreasing the likelihood of failure to comply with the regulations and enable fast track regulatory approvals. Moreover, the findings suggest that establishing ethical AI frameworks that outline principles for transparency, fairness, and accountability, and implementing regular audits, ensures AI systems adhere to these principles. The study has also found that the establishment of a strong data privacy and protection system safeguards sensitive patient and research information and makes it compliant with data protection rules (Sharma & Manchikanti, P 2021).

Based on these findings, the pharmaceutical industry can adopt a practical approach to AI integration. By implementing agile project management methodologies, establishing innovation labs, and conducting regular training sessions, organizations can build a culture of agility and innovation. Launching pilot projects, collaborating with AI startups, and establishing customer feedback mechanisms can refine AI solutions and accelerate their adoption. Investing in AI-driven drug discovery, predictive maintenance, and clinical trial optimization can significantly improve efficiency and outcomes. Furthermore, developing AI tools for regulatory compliance, establishing ethical AI frameworks, and investing in data privacy and security measures are essential for successful AI adoption. By focusing on these practical applications, pharmaceutical companies can effectively integrate AI into their operations, driving innovation and improving outcomes across the industry.

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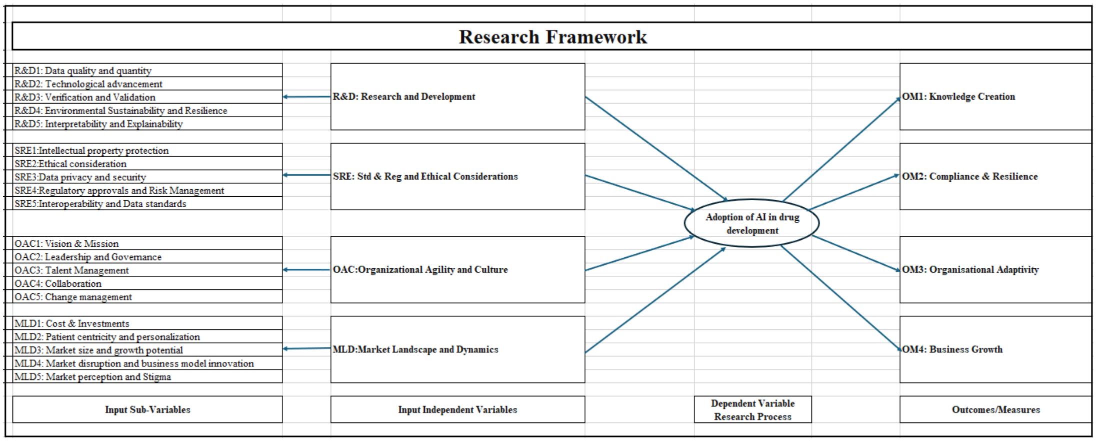
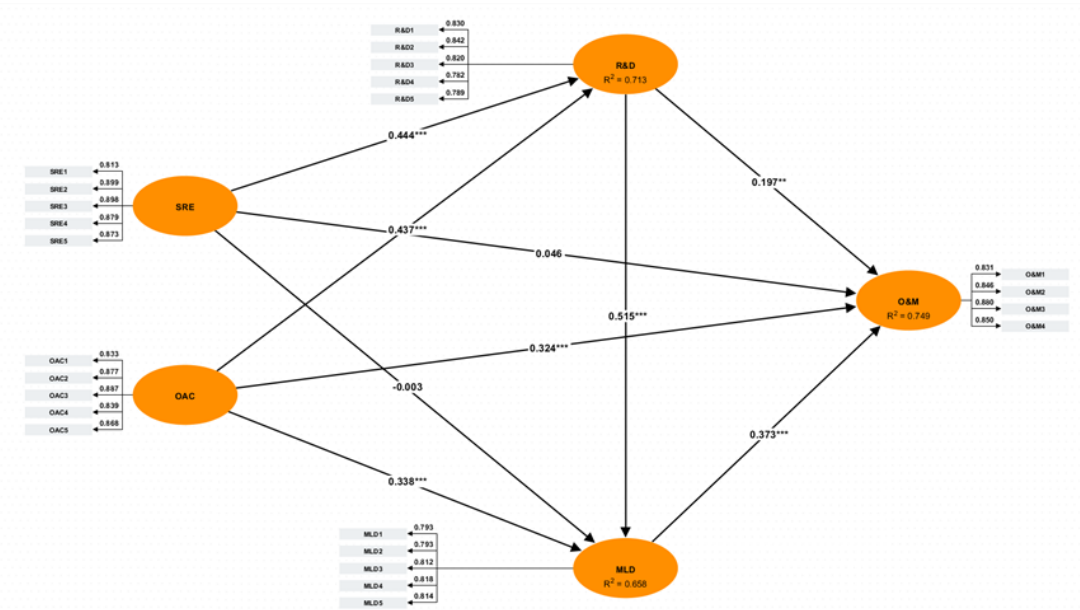
Appendix 1: Research Framework



Appendix 2: Structural Equation Model (SEM)



Appendix 3: Worksheet for Research Questionnaire

Adoption of AI in drug development in Pharmaceutical Industry

Dear Participants,

I, Mugdha Hemant Belsare, Doctorate Scholar at Swiss School of Business Management (SSBM), Geneva, highly appreciate your participation in this research project, which addresses an important topic in business management and satisfies a Doctoral degree requirement.

Purpose of Research Study:

The purpose of this study is to identify and examine the variables that are influential in the adoption of AI In drug development in the Pharmaceutical industry. The study aims to determine what elements make it possible for major Pharma companies to adopt AI in drug development process. CEOs, execs, pharma consultants, policymakers, and academic institutions on a global scale will benefit from the findings.

Factors considered for this research study are as follows:

1. Research & Development (R&D)

2. Standards & Regulatory and Ethical Considerations (SRE)

3. Organizational Agility and Culture (OAC)

4. Market Landscape and Dynamics (MLD)

Instructions:

This study includes an anonymous survey questionnaire. Please read and follow the instructions. The survey should take 5 to 8 minutes. This study has no practical implications and has been designed only for academic research purposes. Data will be treated confidentially.

Informed Consent:

I would like to clarify that this is a personal research project and only for academic research purpose. The data collected will be used solely for the study purpose only.

Thank you for your time and attention.

Sincerely, Mugdha Hemant Belsare

Doctoral Researcher - SSBM, Geneva

* Indicates required question

Your email address*

I voluntarily agree to participate in this research conducted by Mugdha Hemant Belsare, a doctorate student at the Swiss School of Business and Management, Geneva. I understand that my participation is anonymous, and all collected information will remain confidential. I have received satisfactory answers to my inquiries and may withdraw at any time without consequence. I consent to electronically recorded questionnaires and acknowledge that the study results may be published while maintaining anonymity.

Section 2 of 8

2. Research and Development (R&D)

(Please make use of the following scale to indicate the degree to which you agree or disagree with each of the following assertions)

R&D1: Effective AI adoption in drug development hinges on high-quality abundant data, advanced data management and rigorous quality controls.*

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

R&D2: AI-integrated pharma R&D requires technological advancements which enables faster development of new drug discovery.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

R&D3: Verification and validation are crucial in assuring the accuracy and adherence to regulations of AI models used in R&D.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

R&D4: AI-integration in pharmaceutical R&D promotes environmental sustainability by optimizing processes, reducing resource consumption, and developing eco-friendly drug solutions.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

Strongly Disagree (SD)

R&D5: Ensuring interpretability and explainability in AI-driven drug development enhances trust, informed decision-making, and regulatory compliance in pharmaceutical research and development.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

Section 3 of 8

3. Standards & Regulatory and Ethical Considerations (SRE)

(Please make use of the following scale to indicate the degree to which you agree or disagree with each of the following assertions)

SRE1: Intellectual property protection is critical for AI adoption in drug development, safeguarding innovations, encouraging research investment, and ensuring ethical compliance with regulatory standards.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

SRE2: Drug development using AI requires ethical considerations for regulatory compliance, patient privacy, and transparency in AI driven innovations.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

SRE3: The successful integration of AI in pharmaceutical drug development necessitates rigorous implementation of data privacy and security measures to ensure regulatory compliance and ethical management of patient information.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

SRE4: The successful integration of AI into pharmaceutical drug development requires the prioritisation of stringent regulatory approvals and robust risk management.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

SRE5: Ensuring robust interoperability and adherence to rigorous data standards are essential for AI adoption in pharmaceutical drug development, facilitating seamless integration and ethical compliance throughout the process.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

Section 4 of 8

4. Organizational Agility and Culture (OAC*)*

(Please make use of the following scale to indicate the degree to which you agree or disagree with each of the following assertions)

OAC1: The adoption of AI in pharmaceutical drug development should align with organizational vision and mission, fostering innovation and agility to drive transformative advancements.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

OAC2: AI adoption in drug development requires effective leadership and governance to ensure organisational agility and strategic alignment.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

OAC3: Effective talent management is crucial for AI adoption in drug development, fostering agility and innovation by equipping skilled professionals.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

OAC4: Collaboration is crucial for AI adoption in pharmaceutical drug development for enhancing organisational agility, cross-functional team innovation, and cutting-edge medical research.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

OAC5: Effective change management is vital for AI adoption in drug development, ensuring seamless integration, stakeholder engagement, and enhancing organizational agility and innovation.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

Section 5 of 8

5. Market Landscape and Dynamics (MLD)

(Please make use of the following scale to indicate the degree to which you agree or disagree with each of the following assertions)

MLD1: AI adoption in drug development requires cost management and investments to enhance innovation, efficiency, and competitive advantage in the evolving market landscape.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

MLD2: Adopting AI in drug development enhances patient centricity and personalization, aligning with evolving market dynamics to improve treatment outcomes and patient satisfaction.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

MLD3: The adoption of AI in drug development is driven by market size and growth potential, influencing decisions and fostering innovation in the pharmaceutical industry.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

MLD4: Market disruption and business model innovation are pivotal for AI adoption in pharmaceutical drug development, transforming industry dynamics.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

MLD5: Market perception significantly shape AI adoption in pharmaceutical drug development, influencing acceptance, and the uptake of innovative AI-driven solutions in the industry.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

Section 6 of 8

6. . Outcomes and Measures (O&M)

The outcomes that measure the impact of determinants of adoption of AI in drug development in Pharmaceutical Industry

O&M1: Incorporating AI effectively into R&D allows innovation by improving efficacy in drug development, which enables knowledge creation.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

O&M2: Compliance and resilience are key outcomes of AI adoption in drug development, ensuring regulatory adherence and enhancing adaptability to industry challenges.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

O&M3: AI adoption in drug development enhances organizational adaptivity, increasing agility and fostering a culture of continuous innovation in the pharmaceutical industry.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

O&M4: AI adoption in drug development is pivotal for business growth, fostering competitive advantage and unlocking new market opportunities in the pharmaceutical sector.

Strongly Agree (SA)

Agree (A)

Neutral (N)

Disagree (D)

Strongly Disagree (SD)

Section 7 of 8

7. Generic AI and Pharma related information

The following questions are intended for analytical purposes and will not be used for any kind of identification.

This research is carried out with the following factors:

1. Research & Development (R&D),

2. Standards & Regulatory and Ethical Considerations (SRE),

3.Organizational Agility and Culture (OAC),

4. Market Landscape and Dynamics (MLD).

If you believe there is another factor that should be considered in addition to the four above, please indicate the new factors(s) here below:

Your answer

When do you adopt AI in Pharma drug development and technology?

Immediately adopts

Adopt after seeing the trend

Adopt only after recommendation

Adopt gradually

Adopt it leisurely at organisation's pace

Never adopts

Which aspects, in your view, represent substantial hurdles to adopt AI in drug development? (Select all applicable answers)

Check all that apply.

Economic risks

Standard and regulation

Overall funding

Capital investments

Market (information, competition, and size)

Customers (attitude and behaviour)

Operation Cost and Infra set-up costs

Internal culture & mindset

Technology and knowledge

Suppliers

Scarcity of talent and managerial expertise

Leadership style

Other:

Section 8 of 8

8. Respondent Profile

(The following questions are being asked only for analytical purposes and will not be used in any way that would allow individual participants to be identified)

How many years of business, pharma or healthcare experience you have?

Less than 2 years

3 to 8 years

9 to 14 years

15 to 20 years

More than 21 years

What is your most recent and greatest level of education?

Mark only one oval.

Post doctorate

Doctorate

Masters

Bachelors

Diploma

What is your present position or role within the organization?

Mark only one oval.

Chairman/Board of directors

CXO (Business, Tech and Ops)

Senior Management (SVP, VP and Director)

Middle Management (AD/GM, Sr. Manager and Managers)

Subject Matter Experts (Solution Architects, Consultants, Engineers)

User groups and Consumers (Doctors, Clinicians, and technicians)

Other:

Your Current Employment Status

Mark only one oval.

Employed Full-Time

Employed Part-Time

Retired

Self Employed

Contractor

Gender

Mark only one oval.

Male

Female

Other

Location

Mark only one oval.

Europe

Asia

North America

MEA (Middle East and Africa)

Australia and Oceania