HOW CAN BLOCKCHAIN & AI IMPROVE RISK MITIGATION INVENTORY STRATEGIES IN PHARMACEUTICAL SUPPLY CHAINS TO AID WITH RESILIENCE AND REGULATORY COMPLIANCE?

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List of Abbreviation's

PSC	Pharmaceutical Supply Chain
RMI	Risk Mitigation Inventory
AI	Artificial Intelligence
DT	Digital Transformation
IoT	Internet of Things
SCM	Supply Chain Management
KPI	Key Performance Indicator

Abstract

Due to the industry's strict regulations, long lead times and the potentially fatal effects of drug shortages, pharmaceutical supply chains face significant obstacles in their attempts to undergo digital transformation. With product forecasting accuracy as low as 35% and errors as high as 300% in certain markets, traditional Risk Mitigation Inventory strategies reveal significant weaknesses.

Six key themes emerged from the research findings, patient safety serves as the paramount responsibility of pharmaceutical supply chain, requiring RMI levels that extend beyond six months for essential medications. Organisations have considerable forecasting difficulties, with 82.1% continuing to depend on Excel spreadsheets for their operations. Despite widespread recognition of technological potential, current adoption remains limited across the industry. Effective communication and collaboration have been identified as critical success factors in order to adapt digital transformations. Pharmaceutical companies employ diverse risk mitigation strategies that extend beyond traditional inventory management approaches. Finally, the research revealed optimistic future directions for digital transformation initiatives. These findings highlight a crucial disconnect within the pharmaceutical industry. While substantial gaps exist between technological capabilities and actual implementation, several key barriers continue to impede progress. Organisational culture, regulatory compliance requirements, and workforce development challenges represent the primary obstacles to successful technology adoption.

Supply chain resilience and RMI strategies could be greatly enhanced by the introduction of blockchain and AI. However, rather than depending purely on investments in technology successful implementation calls for a comprehensive organisational transformation. The results of the study show how important patient safety is in pharmaceutical supply chains which sets them apart from other sectors. As a result of this the industry needs specific digital transformation strategies that simultaneously address current operational, cultural, and regulatory challenges within the sector.

1.0 Introduction

This research will cover a couple of topics due to the complexity of pharmaceutical supply chains, (PSCs) which are shaped by strict regulatory compliances within the industry. With their supply chains influenced heavily by these regulations' technological advancements, innovations, and globalised manufacturing networks. In this sector, supply chain management (SCM) is significantly dependent on regulatory requirements, including Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP), which ensure safety, efficacy, and quality at every stage of the process (Research, 2024). Due to these traits, PSCs tend to be dynamic, requiring constant innovation and operational adaptation (Kang, Ma, and Shi 2022).

The way PSCs operate is being transformed by technological advancements, particularly in the areas of artificial intelligence (AI) and blockchain. Blockchain records every transaction in a medical products database digitally, improving data accessibility, auditability, and accuracy. As a result, regulations are followed and the risk of counterfeit pharmaceuticals getting into the supply chain is removed. PSCs can react more quickly to issues like shifts in demand or delays in transit by using AI to make better decisions and apply predictive analytics. Together, these innovations improve security and regulatory compliance while fortifying and streamlining procedures to ensure a consistent supply of life-saving drugs (Taherdoost, 2023).

1.2 Risk Mitigation Strategies

PSCs face important risks and managing these risks is important because the sector is highly regulated, and the products are sensitive. The main areas to be investigated in greater detail by the research are the running risk mitigation measures that increase supply chain resilience. RMI, dual sourcing, and agility capacity are all components that are available, as stated by (Lucker and Seifert 2017). These strategies are highly beneficial in addressing uncertainties, including fluctuations in demand, disruptions in supply, and economic issues, which have the potential to significantly impact the availability of critical medications.

RMI describes the practice of maintaining surplus stock beyond standard safety thresholds this is to mitigate any unforeseen supply chain interruptions. The extended lead times necessary for drug production, coupled with stringent regulatory protocols in drug manufacturing and distribution, underline the importance of RMI in the pharmaceutical sector. (Lucker and Seifert 2017) state that a well-structured RMI strategy enables companies to sustain demand despite supply disruptions, which can include production failures or delays in raw material procurement. The difficulty is in striking a fine balance between the costs of keeping higher inventory levels on hand and the potential risks of stockouts, which can have disastrous consequences in healthcare settings where the continuous availability of medications is crucial.

1.3 AI and Blockchain Integration

The integration of blockchain into PSCs and RMI tactics can be significantly enhanced by advancements in AI. AI-powered predictive analytics can enhance the management of inventory and demand forecasting, reducing the need for additional safety stock and ensuring a consistent supply. This is done by AI examining and analysing extensive data sets belonging to products helping to identify patterns and potential hazards, like shifts in a products demand forecast, machine learning algorithms can help organisations manage their inventory proactively rather than reactively.

Given that blockchain technology maintains an open and permanent record of every transaction, it also makes the supply chain more secure and easier to trace. This greatly helps with decision-making and improves risk evaluations for PSC departments. This integration will guarantee that it will not compromise product quality or patient safety, and it will also strengthen and improve the efficiency of PSCs overall. (Nehal Ettaloui, Arezki and Taoufiq Gadi, 2024).

2.0 Literature review

2.1.1 Introduction to Pharmaceutical Supply Chain Regulation

The PSC sector is heavily regulated because of its vital importance to public health and safety. This increased regulation is caused by numerous key features unique to the pharmaceutical sector and its operations. The main reason for very strict regulations in the pharmaceutical sector involves the unquestionable importance of patient safety. To ensure patients get medicine that is safe and effective, the quality of drugs must be protected throughout the entire PSC. Groups like the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe have exceedingly strict rules to stop the rampant distribution of fake or low-quality drugs which are strictly enforced by the FDA (Mackey and Liang, 2011). Multiple aspects of SC are examined which include specific restrictions within production, storage, transportation and distribution are among some of these aspects.

The pharmaceutical sector must also strictly adhere to stringent Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) to ensure that medications maintain maximum effectiveness and quality throughout the whole process. These processes have been developed to ensure the consistent production of pharmaceutical products. These measures ensure that pharmaceutical items are properly regulated. Quality requirements appropriate for the intended usage achieve this. The 2008 Chinese Heparin contamination crisis highlights how important the GMP and GDP practices are, a catastrophic pharmaceutical quality control failure where adulterated heparin containing oversulfated chondroitin sulphate (OSCS) caused 81 deaths and 785 severe injuries in the U.S. alone, with global impact across 11 countries (Liu, Zhang and Linhardt, 2009).

Unregulated Chinese chemical plants, economic counterfeiting amid raw material shortages, and inadequate FDA control were among supply chain weaknesses that helped OSCS, a cheap synthetic contaminant that avoids detection by standard tests, find its way into global markets. Strong pharmaceutical quality systems are vital in a globalised production environment, as the crisis highlighted by swift regulatory changes including advanced spectroscopic testing techniques and enhanced supply chain transparency requirements (Liu, Zhang and Linhardt, 2009) Recent studies (www.ema.europa.eu, n.d.) show that applying the GMP and GDP approaches strictly can greatly reduce the hazards of product contamination and deterioration during storage and transportation.

Blockchain technology represents a paradigmatic shift in how pharmaceutical companies can exceed traditional regulatory requirements while establishing new benchmarks for compliance excellence. The technology fundamentally elevates existing standards by providing unprecedented levels of transparency, traceability, and data integrity that surpass conventional regulatory expectations. Through its immutable ledger architecture, blockchain enables real-time monitoring and verification of pharmaceutical products throughout the entire supply chain, creating a level of oversight that was previously unattainable with traditional paper-based or centralised electronic systems (Wang, 2024).

The implementation of blockchain technology directly addresses the core principles underlying pharmaceutical regulation by providing enhanced mechanisms for ensuring patient safety and product quality. Unlike traditional systems that rely on periodic audits and retrospective reviews, blockchain offers continuous, real-time validation of compliance with regulatory standards. This continuous monitoring capability represents a significant elevation from reactive compliance measures to using proactive quality assurance systems that can identify and address potential issues before they can impact patient safety (Agbo, Mahmoud and Eklund, 2019).

There is a great deal of personal information on patients, their products, and the steps used for creating these products produced within the PSC. To adequately protect both patients' personal information and their ideas, regulatory agencies set strict standards for data integrity and information security. (Subbarao et al., 2024) highlights the significance of blockchain technology in ensuring the complete security and integrity of data within the PSC.

The global expansion of the pharmaceutical sector and SC's has prompted various administrations and jurisdictions to align their regulatory standards with one another. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is one current initiative. The council aims to increase the consistency of how pharmaceutical companies comply with and conform to the technical specifications and standards for product approval. This kind of collaboration is essential to improving the global distribution of these medications. It also ensures the highest standards of quality and safety (www.ema.europa.eu, n.d.)

2.1.2 Risk Mitigation and Supply Chain Resilience

In recent years, SC resilience has developed into an essential priority for pharmaceutical companies, this is being driven by growing risks within global supply networks and the serious implications surrounded with medicine shortages (Lücker and Seifert, 2017). The pharmaceutical and manufacturing industries employ several key strategies to mitigate supply chain disruption risks, each offering distinct advantages and operational characteristics. In addition to the standard safety stock levels, RMI is a calculated surplus of excess inventory designed to guard against supply chain disruptions rather than normal demand fluctuations. Through the deliberate establishment and qualification of a backup manufacturing facility that functions as a production backup, a dual source reduces the dependency on a single production source, thereby providing the supply network with flexibility. (Lücker and Seifert, 2017).

Agility capacity refers to the deliberate reservation of unused production capacity at the primary manufacturing site that can be rapidly activated during emergency situations. Unlike traditional capacity planning that aims for maximum efficiency and utilisation, agility capacity intentionally maintains unused production resources as a form of operational insurance. When problems arise in other areas of an organisations supply chain or a products demand spike unexpectedly, this strategy allows organisations to swiftly increase their production output. This strategy demonstrates a fundamental trade-off between resilience and operating efficiency.
Pharmaceutical organisations tactically choose to sacrifice short-term productivity gains in order to preserve the flexibility needed to handle unforeseen emergencies. This might involve maintaining additional production lines, keeping extra equipment on standby or ensuring surplus labour capacity is available that can be called upon when primary production sources are compromised. (Alfalla-Luque, Luján García and Marin-Garcia, 2023).

2.1.3 Mathematical models for assessing Supply Chain Resilience

(Lücker and Seifert 2017) developed mathematical models to determine optimal RMI levels for given Dual Sourcing and Agility Capacity parameters. When no Dual Source is available, their analysis shows that RMI and Agility Capacity can be used as an alternative. Agility Capacity and Dual Sourcing don't seem to be changeable after a Dual Source is set up. Interestingly, the ideal Dual Source production rate can fall as the disruption duration rises over extended disruption intervals.

According to (Lucker and Seifert 2017), there is a new operational metric for measuring supply chain resilience. This metric is defined as $\rho = M / (M + S), P$ in this equation representing the operational resilience, where M is the mitigated demand and S is the stockout perimeter. Compared to simpler metrics, this one provides a more detailed assessment of resilience as it takes stockout quantity and duration into account.

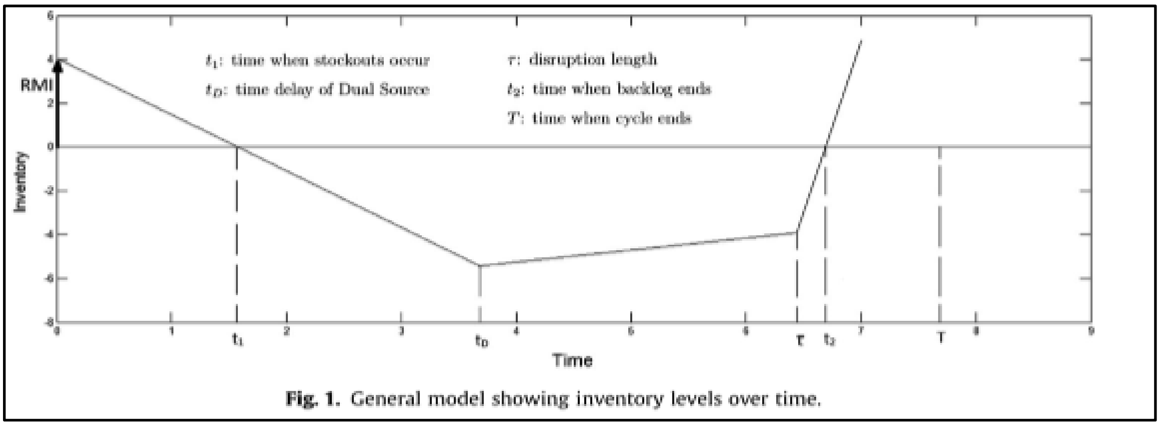

Figure 1: General model showing inventory levels over time(Lücker and Seifert, 2017).

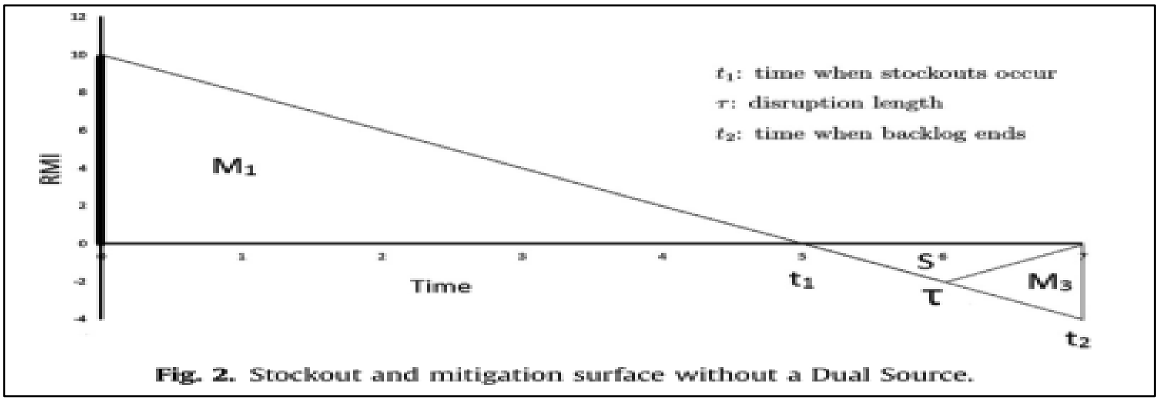

Figure 2: Stockout and mitigation surface without a Dual source (Lücker and Seifert, 2017).

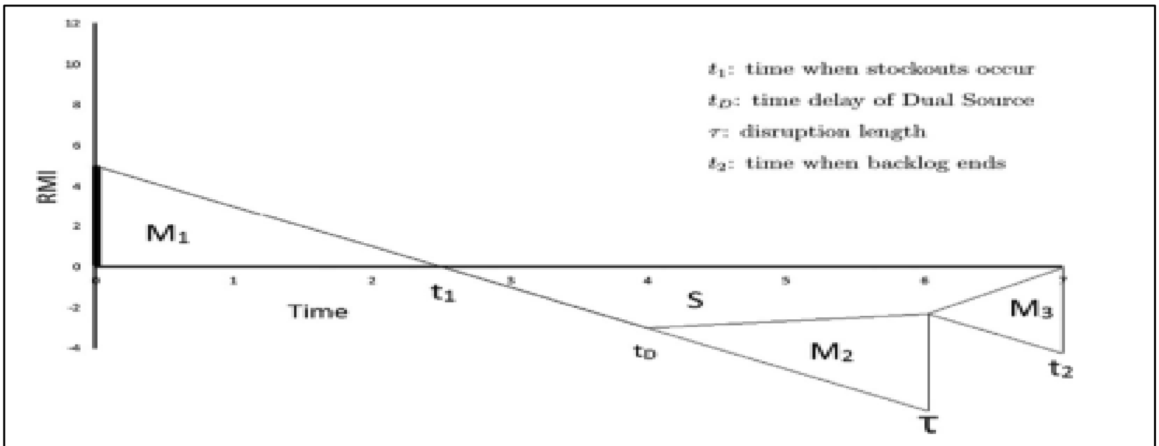

Fig. 3. Stockout and mitigation surface with a Dual Source.

Figure 3: Stockout and mitigation surface with a Dual Source (Lücker and Seifert, 2017).

2.1.4 Measuring Supply Chain Resilience

One obvious operational flaw of the pharmaceutical sector that compromises important business decisions all around the value chain is its reliance on conventional forecasting techniques. With time-series models representing 52% of methods used is PSCs while causal and judgemental approaches represent 24% and 19%, (Pathy and Rahimian 2023) show that traditional forecasting techniques still control the pharmaceutical sector. This dependence on basic techniques such as smoothing and averaging, executed through Excel spreadsheets by 82.1% of organisations highlights a lack of innovation and sophisticated methods in an industry where forecasting errors can have life-threatening consequences.

The inadequacy of these conventional approaches becomes starkly apparent when examining their accuracy rates. Forecasting inaccuracies may reach 40% when employing fundamental techniques, with certain studies suggesting that pharmaceutical forecasts can diverge by as much as 71% from actual outcomes. Research indicates that two-thirds of pharmaceutical forecasts are inaccurate, with over 60% of drug forecasts misestimating peak revenues by more than 40% compared to actual performance. These forecasting mistakes directly compromise several important commercial decisions. Pharmaceutical companies maintaining too high safety stock due to forecast uncertainty show how unstable inventory management decisions are, this leads to higher storage costs and product waste from expiration (Merkuryeva, Aija Valberga and Smirnov, 2019).

The current hurdles in demand forecasting extend beyond methodological boundaries and include market dynamics, data integration issues, product lifecycle fluctuations, and regulatory constraints. The industry's continued reliance on these subpar methods points to internal resistance to the adoption of more advanced technical alternatives. The low adoption rate indicates organisational resistance to change rather than technical challenges, even though current advances in AI and machine learning offer significant benefits through cooperative forecasting that incorporates data from multiple supply chain sites.

2.1.5 Future strategies to enhance Resilience

The pharmaceutical sector is at a pivotal moment in SCM and demand forecasting as more sophisticated ways of forecasting are required due to the growing complexity of global markets and PSCs. Advancements in innovative technologies especially in AI and collaborative forecasting have created major potential to enhance forecasting accuracy. As the sector undergoes substantial development, it is crucial for PSC departments to integrate innovative technologies with their specific expertise. This will strengthen PSC performance and resilience, resulting in superior patient care. (Yani & Aamer, 2022).

Advanced analytics, data processing along with digitalisation have already helped improve PSC operations by addressing inefficiencies and helping to improve decision-making. Advanced sensors and network systems facilitate the automation of real-time production line monitoring, allowing for the immediate detection of any inefficiencies or faults in the products being manufactured (Ibrahim et al., 2024). Predictive analytics uses data processing along with machine learning for demand forecasting, analysing both past and present data together allows for accurate predictions, which leads to a reduction overstocking or stockouts (Pathy and Rahimian 2023). Predictive maintenance further guarantees a consistent production flow by anticipating equipment failures before they occur. Robotic Process Automation (RPA) streamlines repetitive tasks, improves accuracy greatly, integrates smoothly with Industry 4.0 technologies to optimize resource utilization and promotes running efficiency (Yani & Aamer, 2022). Stakeholder communication improves with collaborative platforms that have data visualization tools, so there is more responsiveness to all regulatory changes and every market dynamic. These improvements certainly guarantee functional efficiency, and they greatly increase patient outcomes by delivering life-saving medications in a timely manner.

2..2.1 Blockchains

In the past five years, the emergence of blockchain technology has addressed many challenges faced by many organisations within PSCs and the healthcare sector and this revolutionary solution has drawn important attention for its ability to largely improve efficiency and transparency. (Taherdoost 2023) reports a steady rise in blockchain-related healthcare articles with a notable surge in 2022, indicating growing interest and recognition of blockchain's potential to address recent safety concerns within the healthcare industry. The rising number of research publications demonstrates the considerable growth in the usage of blockchain technology in healthcare.

2.2.2 Applications of Blockchain Technology in Healthcare

Blockchain technology offers many potential benefits, and one benefit is the increased privacy and security it provides for medical records. (Lee et al. 2019) shows how blockchain can securely protect sensitive genetic information, and they depict its use for DNA sequencing data. While (Hölbl et al. 2018) examine all the possible healthcare blockchain applications and focus on how technology might change data management and protect patients' privacy.

The implementation of smart contracts within blockchain-enabled pharmaceutical supply chains represents a paradigmatic shift toward automated compliance monitoring and enforcement. Given that these self-executing contracts continuously monitor handling practices, transfer protocols, and environmental conditions, they can automatically confirm compliance with GDP and GMP regulations. This automation can significantly lessen the administrative burden associated with manual compliance monitoring. As noncompliance can result in serious safety implications this feature is particularly critical for transport of controlled chemicals or temperature-sensitive treatments.

2.2.3 Challenges in Blockchain Implementation

Blockchain technology has many benefits for the healthcare industry, especially when it comes to better data management, security, and privacy. However, its adoption poses significant challenges, including scalability, regulatory compliance, and integration with existing healthcare infrastructure (Taherdoost, 2023). Unlike other sectors, healthcare requires the seamless interoperability of blockchain with legacy systems, which is complicated by stringent regulations and the complexity of existing medical data frameworks.

While blockchain can theoretically be used for a wide range of purposes, its practical application in healthcare is limited by difficulties in developing compliant systems and ensuring compatibility with current technologies. The future success of blockchain in healthcare is likely to be reliant upon its integration with other emerging technologies like AI, which collectively can generate improvements in operational efficiency and patient care (Taherdoost, 2023). The integration of AI and blockchain technology has the potential to enhance the accuracy of diagnostics, simplify administrative processes, and ease the secure authentication of IoT devices.

Despite these opportunities, overcoming the current barriers is essential for realising the full potential of blockchain in healthcare. Failure to address these challenges could hinder the effective utilisation of blockchain, limiting its impact on data security, privacy, and system efficiency. Ultimately if left unresolved these difficulties may prevent the healthcare sector from reaching the anticipated improvements in patient outcomes and operational performance, with significant implications for both healthcare providers and patients (Taherdoost, 2023).

2.2.4 Blockchains Impact on Pharmaceutical Supply Chains

PSCs could be completely transformed by blockchain technology, which increases security, efficiency, and transparency. Blockchain technology is particularly important when combined with cutting-edge technologies like AI and the IoT. PSC operations could be enhanced by using AI-driven analytics to analyse massive volumes of data stored on blockchains while machine learning algorithms can predict shortages of essential medications or medical supplies by analysing historical and current data, ensuring timely distribution and procurement. This maintains data integrity across the entire SC. It also reduces waste and enhances operational efficiency (Subramanian et al., 2024)

The incorporation of IoT enhances SCM by facilitating real-time tracking of medical products. IoT devices, like temperature sensors in cold chain logistics can immediately transfer data to a blockchain network, guaranteeing that sensitive products such as vaccinations remain within specified temperatures during transport. The unchangeable nature of blockchains guarantees that all discrepancies are transparently documented, this decreases the threats of any spoilage in storage or transportation or counterfeit items damaging the SC (Chen et al., 2022).

To guarantee successful implementation, the integration of blockchain into the technical architecture of healthcare necessitates the resolution of scalability, security, and interoperability issues. The management of large medical databases which are continually expanding requires scalability solutions. Researchers are increasingly looking into methods like off-chain storage solutions and sharding, which divides the blockchain into smaller units to increase performance and reduce latency (Kaur et al., 2023). These methods allow blockchain systems to manage large transaction volumes without sacrificing performance.

2.2.5 Economic Implications of Blockchain Adaption

The healthcare industry is starting to adopt blockchain technology, which has raised questions about its potential economic impacts and how it may change the market. The use of blockchain technology has the potential to increase functional performance and eradicate counterfeit goods, both of which have substantial economic benefits. Automating processes within SCM and claims processing has resulted in significant cost savings for healthcare organisations. As a result, the economic effects of data breaches, which leads to billions of dollars in annual costs for the healthcare sector, are lessened to a great extent due to blockchain offering both efficient processes and improved data security, thereby providing the healthcare sector with solutions to persistent issues regarding financial management and data vulnerability (Archana Bathula et al., 2024).

Return on investment studies further show that blockchain technology is financially sustainable in healthcare. Several studies have demonstrated that early adopters experienced substantial returns on investment (ROI) increases within two to three years of implementing blockchain technology. Enhanced efficiency and patient trust are the primary factors driving these increases, the long-term savings and enhanced performance significantly outweigh the initial establishment costs (M. Vimaladevi, R. Thangamani, and Kamalam, 2024).

2.3.1 Advancements in Technologies

Despite the widespread promotion of digital transformation (DT) as an accelerator for operational excellence, transparency, and resilience, real-world data and case studies reveal an additional perspective for PSCs. The integration of technologies like blockchain, AI, and IoT has benefited SCM by enhancing operational efficiency, risk management, and traceability (Moayad Al-Talib et al., 2024) .However the advancement of DT in healthcare and PSCs is hindered by persistent, diverse challenges such as integration with current legacy systems, regulatory complexities, data security issues, and workforce skill deficiencies that collectively decelerate the implementation process and diminish its overall efficiency (Gireesh Kambala, 2024) .Overcoming these obstacles is crucial for the pharmaceutical sector to fully harness the revolutionary capabilities of DT and obtain persistent and continuous operational excellence within PSCs.

The US's Medi Ledger pilot project, which improved recall processes and made safe decentralised tracking possible is one example of how blockchains can work effectively in PSCs, unfortunately these pilot programs usually fall short of achieving industry-wide acceptance, despite the fact they are theoretically sound. This is down to a number of reasons as big pharmaceutical companies are reluctant to fully adopt blockchain technology, which include the high implementation costs, the absence of generally recognised standards and the difficulty of integrating blockchain with deeply embedded legacy systems (Ledger Insights, 2020).The industry seems to adapt a risk-averse mentality where the possibility of operational disruption outweighs potential benefits of innovation.

Novartis's participation with Dataiku's analytics platform highlights the potential and the constraints of data-driven transformation. The company's measurable improvements in forecasting and inventory management were dependent on substantial pre-existing technological proficiency and a large commitment to workforce upskilling. The lack of foundational capabilities leads many industry peers to view similar initiatives as aspirational rather than actionable (Dataiku Community, 2023). The relationship between Pfizer and Eli Lilly in Ireland demonstrates how DT may transform the pharmaceutical industry with its continuous manufacturing capabilities. Pfizer and Eli Lilly preformed a 95-hour uninterrupted production run which was achieved using continuous crystallisation, isolation, and drying (CCID) technology; this shows what can be achieved when top companies work together (Domokos et al., 2021). Unfortunately this scenario also shows the systemic inequality in the industry, most organisations can't afford large scale innovation due to capital constraints, regulatory uncertainties, and a lack of digital expertise required. This suggests that DT could potentially increase the gap between the industry's leaders and smaller organisations, which could harm the sector as a whole.

The regulatory system, while designed to enhance safety and quality, often yields unexpected repercussions. Despite the extensive investment in serialisation and electronic tracking mandated by the EU Falsified Medicines Directive (FMD), smaller market participants have expressed concerns regarding the operational burden of compulsory pack scanning, which impedes distribution and escalates costs. In addition, contrary to DT's goals, the implementation of the directive has revealed that European markets remain unharmonized, resulting in fragmented compliance efforts and inefficiencies (Van Baelen et al., 2017).

The situation is further complicated by worries about data security and privacy, this is due to their reliance on cloud computing and other interconnected systems meaning pharmaceutical companies are a popular target for attacks by cybercriminals (Manufacturingchemist.com, 2021). Tech giants like Siemens have proven that temperature sensitive products can be effectively monitored through IoT, but these developments also increase the likelihood of data breaches and regulatory compliance fines especially in countries operating strict data protection laws (Cil, Abdurahman and Cil, 2022). That is why the industry's cautious stance towards digitalisation is a sensible reaction to the actual and growing risk environment and not just a result of traditionalism.

Cultural resistance within pharmaceutical organisations also poses as a significant barrier to DT, top level personnel in the sector is typically committed to traditional practices, and the implementation of new technologies is often met with distrust or resistance. Case studies indicate that even well-funded companies encounter difficulties in securing buy-in without continuous investment in change management and clear communication. Biopharma companies who have effectively implemented new digital platforms have achieved this by incorporating support systems, these systems include specialised helpdesks and ongoing training, these tactics can be resource-demanding and challenging to replicate on a large or global scale (Ullagaddi, 2024).

The obstacles currently slowing DT within the pharmaceutical industry are fundamentally rooted in structural, cultural, and regulatory contexts. An effective and successful advancement and improvement of systems requires more than just an initial technological investment, it must involve a strategic, progressive approach customised to organisational readiness, proactive change management, and a commitment to collaborating with regulators and partners in the co-development of standards and solutions. Failure to address these fundamental difficulties in the industry continue the current cycle of pilot initiatives and marginal improvements in PSCs and the healthcare sector. (Hole, Hole and Shaw, 2021)

3.0 Research Question

How can Blockchain and AI improve Risk Mitigation Inventory strategies in Pharmaceutical Supply Chains to aid resilience and regulatory compliance?

3.1 Importance of the Research

Global PSCs confront a unique convergence of challenges. Stringent regulatory oversight, long and inflexible production lead times, temperature-controlled logistics the ethical obligation of ensuring continuous patient access to essential life-saving medications. Even very short lived stock-outs can lead to critical patient harm and substantial reputational damage. Traditional safety-stock formulas and manual spreadsheet forecasting—still used by 82% of firms interviewed—are proving insufficient in this increasingly volatile environment.

Blockchain offers an immutable, real-time ledger that can unify fragmented data across manufacturers, logistics providers, and dispensers, thereby strengthening auditability and counterfeit detection. AI, when fed with high-fidelity, blockchain-secured data, can move forecasting from reactive to prescriptive by flagging nascent demand surges, transportation bottlenecks, or quality-control deviations weeks in advance. The simultaneous application of both technologies therefore represents a step-change in how inventory buffers are sized and deployed.
Moreover, regulatory agencies such as the FDA and EMA are signalling growing acceptance of digital record-keeping and automated lot tracing. By addressing the twin goals of resilience and compliance, this study not only fills a critical gap in the literature but also offers actionable guidance for practitioners seeking to modernise pharmaceutical supply networks in line with Industry 4.0 principles.

4.0 Methodology

4.1 Introduction

This study seeks to improve existing SC RMI methods by exploring the integration of blockchain technology and AI to develop more effective RMI strategies. Enhancing PSC resilience through the reduction of stockouts and the assurance of a consistent supply of essential medicines would significantly benefit numerous healthcare systems. The authorities rigorously establishes stringent regulations to ensure the pharmaceutical business upholds the excellent standards. These regulations protect safety and provide traceability for customers and patients. Transparency and data integrity can be enhanced through the integration of many different aspects of blockchain technology. Regulatory compliance is aided by these improvements. It reduces the possibility that fake goods will make it into the SC.

The combination of AI's predictive analytics capabilities and blockchain's secure data sharing could revolutionise inventory management, potentially reducing costs while maintaining or improving supply chain performance. This connectivity throughout the SC has the potential to offer precise data in real-time which enables better and faster decision-making in reaction to demand changes or disruptions.

Lücker and Seifert's running resilience measure, ρ = M / (M + S), are measures of SC resilience metrics that can be significantly enhanced by future study. This research identifies how blockchain and AI increase RMI strategies, and it reveals the best combinations of RMI, Dual Sourcing and Agility Capacity.

During the process of the completion of more research, the viability of incorporating these technological advancements into PSCs will be studied further. Additionally, this study will conduct an analysis of some of the concerns that were brought up, such as maintaining scalability while complying to rules and regulations. For the purpose of significantly increasing regulatory compliance and lowering the number of counterfeit pharmaceuticals that are found in the SC, researchers are investigating the various methods in which enhanced traceability and stronger data integrity can be implemented within the SC. For the purposes of this investigation the primary emphasis is placed on improving the procedures that are already in place which are founded on traditional forecasting methodologies. The goal would be to discover strategies that are more efficient in forecasting demand in a reliable manner. As a result of the research, it is anticipated that a significant number of errors will be reduced, and significant improvements in efficiency will take place. The resilience, efficiency and compliance of PSCs will be improved as their DT occurs. As a result of the research, it is anticipated that a significant number of errors will be reduced, and significant improvements in efficiency will take place. The resilience, efficiency and compliance of PSCs will be improved as their DT occurs.

4.2 Expected Outcomes

Practical understandings are sought to be provided by exploring how blockchain and AI are integrated in RMI strategies. This exploration could importantly improve the ability to manage risks in the industry. These enhancements will help ensure a steady supply of important pharmaceuticals, the aim of this study will be to investigate potential consequences for the pharmaceutical industry and if they will result in stronger and more efficient supply chains. The research's findings should indicate if supply chains can endure more disturbances helping to ensure the continuing availability of life-saving medications.

The research is expected to reveal how DT can streamline regulatory compliance processes, potentially reducing administrative burdens and enhancing audibility, considering the intricate regulatory framework in the pharmaceutical sector this is especially important. Measurable improvements in supply chain performance such as shorter lead times in manufacturing, lower inventory holding costs, more accurate forecasting and improved supplier relationship management are among the expected results. These highly quantifiable benefits will strengthen the business case for the adoption of DT in PSCs.

The research aims to contribute to the development of more resilient pharmaceutical supply ecosystems capable of withstanding diverse disruptions, from natural disasters to geopolitical tensions. By providing robust evidence of the benefits of integrated blockchain and AI solutions, the study aspires to influence strategic decision-making within pharmaceutical organisations and inform policy discussions on supply chain security in critical industries. The results should show whether supply chains can withstand more disruptions in exchange, ensuring the continuous supply of life-saving drugs and advancing the more overall goal of better public health outcomes for everyone.

4.3 Research Design

This study employs an inductive research design, ideally suited for examining the intricate relationships among blockchain technology, AI, and RMI techniques in PSCs. This method facilitates the development of new concepts and patterns from the data, rather than evaluating pre-existing theories. Given the rapidly developing nature of these technologies and their applications in SC management, an inductive methodology provides the necessary flexibility to include unexpected findings and new directions that may emerge throughout the research process.

The core research tool for this study consists of a series of semi-structured interviews aimed at examining key themes. The purpose of the interviews is to gain a better understanding of the current RMI approaches and the incorporation of blockchain and AI technologies in PSCs. Also its effects on SC resilience and regulatory compliance, as well as any of the obstacles and benefits that were encountered during the implementation process itself. The interview questions have been carefully crafted to collect useful information about the current or future use of these technologies in PSCs, with an emphasis on how they can enhance resilience and regulatory compliance. The interview design process began with an in-depth review of existing literature to identify the primary concepts and limitations in current thinking. This directed the development of a preliminary set of questions, later improved through collaboration with professionals in the field. The use of a semi-structured approach allows for the opportunity to find new interesting topics during the talk while also guaranteeing that all important themes are fully addressed.

A pilot study will be conducted with the initial interviewer to assess the effectiveness of the interview questions this will facilitate the further refinement of the questions and the identification of any gaps in topic coverage ahead to the commencement of the main study. The interviews are anticipated to occur across two to three months with each meeting lasting between 30 to 45 minutes. The interviews will be held both in-person ideally and online depending on the participants choice.

Data collection will be conducted through structured surveys, performance metrics analysis, and secondary data extraction from organisational databases and public records. The study will employ cross-sectional data collection techniques to capture current practices and performance indicators across multiple PSC organisations. Key variables will include operational efficiency metrics, compliance scores, risk mitigation effectiveness, and technology adoption rates.

4.4 Philosophical Assumption

In the area of PSC management, the integration of AI and blockchain technology represents not just a technological advancement, it reflects a significant transformation in our theoretical framework to manage complex systems. The established views regarding trust, transparency and decision-making in highly regulated contexts necessitate re-evaluation in light of this potentially substantial change.
The study's central argument is that data interaction and human activity make PSC realities dynamic, rather than static. A new theoretical framework for comprehending and controlling SC dynamics emerges when the predictive capabilities of AI are combined with the immutable database of blockchain. The concept is that knowledge in this context is actively produced through the integration of huge data streams and mathematical ideas, rather than merely seen or recorded.

Moreover, the study's focus on practical applications and solutions to industry challenges reflects a pragmatic philosophical stance. It asserts that the value of knowledge lies not in abstract theorization but in its ability to effect tangible improvements in real-world scenarios. This pragmatism is tempered, however by an acute awareness of the ethical implications of deploying such powerful technologies in a domain directly impacting human health and wellbeing.

While these technologies are praised for making things more open and compliant with rules, they also bring up important questions about who is responsible in systems that are becoming more and more automated. This research encourages a re-evaluation of the ontological and ethical principles underlying SC management in the pharmaceutical sector. It indicates a future in which the differences between human judgement, algorithmic decision-making and regulatory monitoring become progressively vague. Thus requiring an innovative philosophical framework to address the complex nature of this developing environment.

4.5 Data Collection Methods

The qualitative strand utilises thematic analysis to interpret data collected from semi-structured interviews with supply-chain practitioners. The process begins with familiarisation, where interview transcripts are read and listened to multiple times to immerse the researcher in the data and gain a comprehensive understanding of participants' perspectives. Initial coding follows, with segments of text relevant to the research questions systematically coded. Codes are generated inductively, allowing themes to emerge organically from the data rather than being imposed a priority. These codes are then grouped into potential themes that capture significant patterns or insights related to Risk Mitigation Inventory (RMI) strategies, digital adoption and regulatory compliance. Identified themes are reviewed for coherence and distinctiveness, with overlapping or ambiguous themes refined, merged or separated as necessary to ensure clarity and analytical depth. Each theme is clearly defined and labelled to encapsulate its core meaning, supported by illustrative quotes from the interviews. The final report presents each theme in detail, highlighting key findings and their implications for pharmaceutical supply-chain management.

4.6 Limitations

This research targets to give key understandings to the integration of blockchain and AI technologies in PSCs, while recognising multiple limitations. This research used a particular cross-sectional design. It is concentrating only on current states, and not on how they change because of this limitation, the wide-ranging effects of blockchain technology and AI on the pharmacy business might not be widely understood.

Even though the semi-structured interview should provide much in the form of useful information, it may not be fully representative regarding the PSC operations overall due to the small number of participants. Since blockchain and AI are still new to PSCs, some participants may not have much experience with them. This could lead to answers that are based on speculation instead of experience.

The pharmaceutical industry is subject to stringent and evolving regulations The current state of rules might affect the outcomes of the research. These rules could change quickly, resulting in the outcomes might become less valuable in the future. The aim of the research is to identify potential advantages of mixing blockchain and artificial intelligence, however it may not highlight how difficult these technologies are to implement into PSCs .

The accessibility and quality of quantitative data regarding blockchain and AI integration in PSCs may be limited, which may impact the accuracy of statistical research. The reliance on interviews can lead to self-reporting bias, as individuals may overstate the benefits or minimise the challenges associated with technology implementation.
The study's focus on blockchain and AI may neglect other developing technologies that could influence PSC management.

4.7 Ethical Considerations

All of the participants shall be given a complete account of the study's objectives as well as procedures before interviews or the gathering of data occurs. Informed consent will be gathered by the signing of a consent form. Additionally, the voluntary nature of participation coupled with the right to withdraw at virtually any moment without repercussions will be highlighted..
The research proposal will be presented to the college's ethical committee for evaluation and approval prior to initiating any data collection or participant involvement. Any recommendations or amendments proposed by the ethics committee will be carefully implemented. It also seeks to enhance PSC management by addressing ethical considerations and maintaining the highest standards of ethical behaviour and social responsibility

4.8 Pilot Study

This pilot study framework is designed to test and refine the methodology for the main dissertation research on integrating blockchain technology and artificial intelligence to enhance Risk Mitigation Inventory strategies in pharmaceutical supply chains. The pilot study will evaluate the feasibility of the proposed semi-structured interview approach, validate research instruments and provide preliminary insights to inform the full-scale study. The pilot study aims to test the effectiveness and clarity of the semi-structured interview guide while assessing the feasibility of participant recruitment within the pharmaceutical supply chain sector. The research will evaluate the appropriateness of the research methodology for addressing the research question and identify potential challenges in data collection and analysis procedures.

The study seeks to gather preliminary insights on blockchain and AI integration in pharmaceutical supply chains while testing the researcher's interviewing skills and competence. Additionally, the pilot will refine the interview questions based on participant feedback and researcher observations, and estimate the time required for each interview and overall data collection process.

After the pilot study was completed with two participants who had decades of experience in PSCs, a number of questions were revised to facilitate more open-minded responses. This was necessary because some of the questions were excessively focused on a specific area or initiative.

5.0 Analysis and Findings

5.1 Qualitative Analysis

This research aims to enhance the resilience and regulatory compliance of PSCs by examining the potential of blockchain and AI to enhance RMI strategies and resilience , understanding the practical implications of emerging technologies is both crucial and timely as PSC become more and more complex while being subject to rigorous monitoring. This study conducts a qualitative analysis aimed at illuminating the intricate processes associated with the integration or adoption of blockchain technology alongside AI and IoT. It explores the advantages and challenges faced by industry professionals, as well as the evolving best practices that are currently influencing SCM. The interviews should provide valuable insights directly from PSC members, making them the selected primary data source. This method facilitates a comprehensive examination of existing practices in conjunction with the core motivations, uncertainties, and expectations related to DT within the industry. The aim of the qualitative analysis is to gather firsthand accounts and expert perspectives from individuals working in the pharmaceutical supply chain sector.

Interviewee Index

Interviewee No.	Interviewee Role	Years of Experience in PSCs	Prefix
1	SC Executive	10+ years	SE1
2	SC Executive	15+ years	SE2
3	SC Planner	5+ years	SP1
4	SC Director	18+ years	SD1
5	SC Planner	15+ years	SP2

Figure 4: interviewee Index

Table of key themes and insights

Theme	Key Findings	Interviwee Prefix
Stockout Implications	Direct impact on patient safety; high planning complexity for critical products (e.g., oncology)	SE1
Forecasting Challenges	High forecast inaccuracies; reliance on traditional SAP-based methods; manual oversight needed	
Communication & Collaboration	Essential both internally (compliance/alignment) and externally (vendor management)	
Technology Adoption	Slow, cautious; SAP dominant; AI and automation emerging but not yet mainstream	
Barriers to Digital Transformation	High data/compliance burden; slow adoption, especially in large firms; need for robust systems	

Figure 5: Themes and Insights Interviewee No.1

Theme	Key Findings	Interviwee Prefix
Inventory and Oncology	High raw material inventory in oncology; KPIs on inventory targets; financial burden from poor initial operations	SE2
Forecasting and Demand	Traditional methods lead to inaccuracies; need for improved strategies and alignment with changing markets	
Technology and Systems	SAP upgrades in progress; no AI implemented; traceability managed via ERP; lack of digital dashboard	
Collaboration and Roles	Siloed teams, especially with colleagues in different time zones; internal and cross-department collaboration essential; lack of role clarity	
Transparency and Integration	Lack of transparency and system linkage hampers efficiency; Brexit complicates traceability and compliance	
Future Priorities	Enhanced batch trace management; improved visibility in SAP CPP; greater collaboration with subcontractors	

Figure 6: Themes and Insights Interviewee No.2

Theme	Key Findings	Interviwee Prefix
Risk Mitigation & Inventory	High risk mitigation inventory (RMI) and dual sourcing are critical strategies, but regulatory and process barriers limit their universal application.	SP1
Operational Challenges	Long lead times and unreliable demand forecasting contribute to inefficiencies and increased costs, mainly through stock expiry and disposal.	
Technology & Automation	The absence of AI and reliance on traditional systems make supply chain operations highly administrative and slow to adapt to demand fluctuations. Automation is present in warehousing/packaging but not in supply chain management.	
Regulatory Environment	Stringent regulations put additional pressure on quality departments and slow the pace of innovation.	
Potential for AI & Transformation	There is significant untapped potential for AI and automation, particularly in procurement and administrative functions, to improve efficiency and resilience in the supply chain.	

Figure 7: Themes and Insights Interviewee No.3

Theme	Key Findings	Interviwee Prefix
Product Management	Traditional planning methods still dominant; oncology products particularly challenging; 35% forecast accuracy extremely difficult	SD1
Regulatory Compliance	Complex cataloguing/aggregation requirements; different market regulations; blockchain potential for traceability	
Technology Integration	Touchless planning as ultimate goal; AI integration planned; new systems for RDC/LCC tracking	
Operational Challenges	Current systems need upgrading; resistance to technology adoption; patient safety concerns	
Supply Chain Resilience	AI potential for helping unpredictable challenges; need for adaptive responses; investment in training essential	
Innovation Barriers	Regulatory constraints; need for skilled teams; alignment crucial for implementation	

Figure 8: Themes and Insights Interviewee No.4

Theme	Key Findings	Interviwee Prefix
Risk Mitigation & Inventory	High risk mitigation inventory and dual sourcing are critical strategies to ensure constant medication availability	SP2
Operational Challenges	Long lead times and unreliable demand forecasting contribute to inefficiencies and increased costs, mainly through stock expiry and disposal.	
Data and People challenges	Data accuracy extremely important to fix before DT can occur. Investment in people essential for succuseful implementaion	
Technology & Automation	The absence of AI and reliance on traditional systems make supply chain operations highly administrative and slow to adapt to demand fluctuations.	
Potential for AI & Transformation	There is significant untapped potential for AI and automation, particularly in procurement and administrative functions, to improve efficiency and resilience in the supply chain.	

Figure 9:Themes and Insights Interviewee No.5

5.2 Thematic Analysis of Interview Findings

Theme 1: Patient safety a unique supply chain priority

The pharmaceutical industry is distinct from other industries primarily because disruptions within the PSC directly affect patient safety, this component criticality highlights how inventory shortages have a much more serious impact compared to companies operating in different industries. SP2 mentions that to decrease RMI and boost resilience, PSCs first requires more accurate and reliable forecasts from across all markets and in storage, especially for products that have high-risk repercussions such as oncology medications. RMI typically exceeds six months for oncology items, compared to the typical three-month stock for other product categories, oncology products require extensive planning and replenishment schedules in order to guarantee a consistent supply as a result SCM becomes more complex due to the higher RMI levels. SP1 mentions that this demands substantial administrative work to maintain a steady supply and a RMI target suitable for organisational goals. SD1 emphasised that oncology products ,owing to their specialised nature and extended replenishment intervals (RMI often exceeding six months) demand even more cautious planning to avert critical shortages. SD1 observed that oncology demand forecasts achieve at best 35% accuracy in some markets, rendering stock-out risks particularly acute and underscoring the need for redundant safety stock and robust cross-market coordination to uphold patient safety targets.

Theme 2: Forecasting challenges and inventory management

The major difficulties involved in managing inventory portfolios and forecasting demand within PSCs were a recurring theme in the interviews. The main cause of these issues is the unpredictable and inconsistent demand for products according to interview data, forecast errors in some markets can reach as high as 300%.This results in a difficult balancing act between keeping enough inventory on hand to prevent life-threatening shortages and reducing the financial burden of holding excess inventory. In particular SE2 emphasised how inadequate inventory management can cause major SCM burdens, especially for high-cost and potentially lifesaving oncology products. KPIs for inventory were emphasised as a priority area to track current issues in SCM with future system upgrades on SAP ERP designed to address these issues from occurring. SP1reinforced this theme by noting that extended lead times, coupled with inefficiencies in demand forecasting, often result in stock expiring before use, leading to costly disposals for the organisation. The challenge is especially acute in oncology products, where stockouts can have severe repercussions, and the limitations of traditional demand forecasting methods increase the risk of shortages or surplus inventory. All interviewees, including SD1, highlighted the limitations of traditional demand-forecasting approaches. SD1 described manufacturing capacity constraints that can precipitate stock-outs when new oncology products launch, compounded by very limited historical data. SD1 noted that maintaining “adequate stock” relies heavily on employee mind-sets and manual cataloguing, but this method struggles to accommodate the high uncertainty of oncology demand. SP2 mentions forecasting and data quality as essential areas for improvement as these problems can lead to bad decision making such as products having to be disposed etc. SP2 emphasises that forecasting challenges must be addressed in order to improve RMI strategies and resilience.

Theme 3: Current technological landscape and adoption

According to the interviewees, PSCs adopt DT slowly and cautiously. Although the transformative potential of DT is widely acknowledged, actual implementation is still scarce and dispersed throughout the industry. With ongoing initiatives to integrate AI capabilities in the future, like SAP S/4HANA implementations, SAP remains the leading enterprise resource planning system. The industry takes a measured approach to DT as it places a higher priority on operational stability and regulatory compliance than on rapid innovation. New technologies are only adopted following extensive validation and testing processes to ensure they meet the stringent requirements of pharmaceutical manufacturing and distribution. SE1 pointed out that even though new technology is becoming more visible, forecasting still needs to be strategically improved in order to meet changing market demands. It was specifically noted that current systems lack AI, while traceability is only managed by ERP solutions rather than more sophisticated technological methods. SP1 acknowledged that their company does not currently use AI in its supply chain planning operations, describing as extremely labour-intensive and administrative as it depends on traditional systems. Automation is common in packaging and warehouse operations, but it hasn't been applied to SCM, which limits the potential for efficiency improvements and keeps manual processes in place that could be improved with DT. SD1 confirmed that traditional planning methods remain dominant and that new systems for Regional Distribution Centre (RDC) and Local

Coordination Centre (LCC) tracking are only just being rolled out. No interviewee currently uses AI for core SCM; instead, ERP solutions handle basic traceability. SD1 explained that the ultimate goal is "touchless planning," where integrated AI can autonomously optimise materials and constraints—yet current systems and master data require significant upgrading before such capabilities can be realised. SP2 has seen no AI capabilities yet within their work.

Theme 4: Communication and collaboration as critical success factors

Effective communication and collaboration emerged as indispensable elements of supply chain management across all interviews. This theme manifested both within organisations and with external partners in the supply network. Internally, the stringent quality guidelines and compliance requirements that define the pharmaceutical sector necessitate robust cross-functional teamwork and alignment. Externally, close collaboration with vendors is essential to mitigate the risk of supply chain delays, which can have cascading effects on production schedules and, ultimately, patient access to critical medications.

SE1 identified operational silos as problematic, highlighting that the oncology team functioned in isolation and that collaboration on new product start-ups represented a critical area for development. Concerns regarding insufficient transparency, ambiguous roles, and the lack of a digital dashboard were identified as obstacles to comprehensive planning and the effective execution of supply chain strategies. SP1 highlighted the importance of team building and a clear distinction of roles and responsibilities for ensuring compliance and operational success in PSCs. The existing absence of system integration has been recognised as a major obstacle to efficiency within the organisation, obstructing information flow and hindering collaborative decision-making processes essential for effective SCM. Effective cross-functional teamwork and external vendor alignment are critical success factors. SD1 reinforced earlier findings that organizational silos—especially between oncology teams and broader SCM functions—impede end-to-end visibility. The absence of a digital dashboard and fully integrated systems obstructs collaborative decision-making and impairs rapid response capabilities. SP2 mentions that current DT implementation is slow due to gaps in communication between strategic and operational teams a lack of coordination is seen as in issue.

Theme 5: Risk Mitigation strategies

The interviews revealed multiple advanced strategies for RMI in PSCs, with high RMI levels consistently identified as the preferred approach, particularly for critical oncology drugs. In light of supply disruptions and challenges in forecasting, this strategy effectively ensures product availability. Yet it has substantial cost ramifications that need to be properly managed. Another important risk-reduction strategy that was found to be effective was dual sourcing. SP1 however, stated that because of the intricate procedures involved in vendor approvals, not all products can benefit from dual sourcing. This restriction makes decisions about inventory management more difficult and increases exposure to supply disruptions, calling for more advanced methods of risk assessment and mitigation.

SD1 states that the regulatory environment significantly influences risk management approaches, placing substantial pressure on quality departments to manage high volumes while ensuring compliance. The regulatory burden limits flexibility and hinders the adoption of innovative practices, resulting in a conflict between the necessity for agility in supply chain operations and the requirement to uphold stringent quality standards and regulatory compliance. The participants in the interviews highlighted that this tension represents a core challenge in pharmaceutical SCM, requiring sophisticated strategies and collaboration to effectively balance different goals and objectives.

Theme 6: Future directions and opportunities for Digital Transformation

Despite current limitations all interviewees conveyed a sense of optimism about the potential of DT in pharmaceutical SCM. They anticipated that future developments would include a growing influence of AI on supply chain planning, especially in the areas of monitoring key performance indicators, improving forecasting accuracy, and reducing administrative tasks. SP1 states automation of purchase order creation and implementation of automated boundaries for inventory management were seen as promising applications of emerging technologies. Continued growth in automation of packaging operations was expected to extend to other areas of the PSC and increasing automation of administrative tasks was viewed as an important opportunity to reduce workload and improve efficiency.
According to SP1, AI could offer significant benefits in aiding administrative and purchasing procedures, including automatic ordering when stock levels reach a predetermined threshold. The broader potential of AI to reduce the current administrative load was also highlighted implying that DT might successfully solve a number of inefficiencies currently present in pharmaceutical SCM. An understanding of the difficulties in implementing new technologies in a highly regulated environment, however, somewhat dampened the initial optimism. Nonetheless, it was believed that the expected benefits outweighed the costs required to overcome these obstacles.

SD1 identified optimized lead-time reduction, quality monitoring, and in-sight tracking as immediate benefits of emerging tech. All participants anticipated broader AI adoption for forecasting accuracy, automated ordering, and administrative relief. SD1 noted the potential for blockchain to enhance product traceability end-to-end, though full implementation remains aspirational. Investment in training and skilled teams was underscored as essential to bridge the gap between DT ambitions and regulatory realities.SP2 identifies internal alignment from the top down as a critical point for DTs success in PSCs.

5.3 Barriers to digital transformation

The interviews identified several significant barriers to digital transformation in pharmaceutical supply chains that must be addressed to realise the potential benefits of emerging technologies. Significant obstacles to DT arise from the extensive data involved, integrating old systems and the rigorous compliance standards in the pharmaceutical sector, posing considerable difficulties for organisations aiming to adopt innovative technological solutions. The natural hesitation of large organisations to alter established processes significantly hinders industry-wide innovation. Additionally, the necessity for comprehensive development and validation of reliable systems and software to meet the rigorous standards of pharmaceutical manufacturing and distribution enhances this challenge.

Lack of system integration across departments was identified as a particular challenge, limiting the potential for end-to-end visibility and coordination in supply chain operations. Further complicating matters, the lack of digital dashboards that support end-to-end planning prevents decision-makers from obtaining a comprehensive view of supply chain performance or identifying areas for growth and improvement. The need for compliance and the desire for more responsive and flexible supply chain operations are at odds because of regulatory restrictions that limit flexibility and slow innovation.

The combination of these challenges explains the pharmaceutical sector's measured stance towards DT. The potential benefits of new technologies are widely recognised, yet their implementation is littered with challenges that necessitate meticulous planning and substantial financial commitments. The interviewees suggested that addressing these barriers will require a combination of technological innovation, organisational change, and regulatory evolution to create an environment more conducive to digital transformation in pharmaceutical supply chains.

The pharmaceutical industry is at a critical juncture, according to the thematic analysis of interview data, the ability of DT to address persistent problems in forecasting, inventory management, and operational efficiency is becoming more widely recognised, despite the current dominance of traditional systems and methodologies in the sector. The unique priority placed on patient safety creates both urgency for improvement and caution regarding implementation of new technologies, resulting in a measured approach to innovation that balances the potential benefits of emerging technologies against the risks of disruption to pre-established processes.

The findings suggest that successful DT in PSCs will require addressing not only technological barriers but also organisational factors such as communication, collaboration, and clearly defined roles and responsibilities. As the sector continues to evolve, the integration of AI, blockchain, and other advanced technologies like IoT holds promise for enhancing RMI strategies and improving overall supply chain resilience and compliance. However, realising this potential will require a coordinated effort across multiple dimensions, including technological innovation, organisational change, regulatory evolution, and industry collaboration to create an environment conducive to meaningful transformation while maintaining the stringent standards of quality and safety that define the pharmaceutical sector.

6.0 Discussion

This research investigated how blockchains and artificial intelligence can enhance Risk Mitigation Inventory strategies in pharmaceutical supply chains in order to improve resilience while ensuring regulatory compliance. The qualitative analysis supported by industry insights and a thematic examination of current practices reveals both significant opportunities and substantial barriers that shape the implementation landscape for these emerging technologies.

6.1 Interpretation of Key Findings

The research confirms that pharmaceutical supply chains operate under fundamentally different constraints compared to other industries, with patient safety serving as the overriding priority that influences all operational decisions. This finding directly addresses the research question by demonstrating that any technological enhancement to RMI strategies must prioritise patient safety over traditional supply chain efficiency metrics. Interview data revealed that oncology medications require RMI levels exceeding six months, compared to the typical three-month stock for other product categories. This finding reinforces Lücker and Seifert’s assertion that pharmaceutical supply chains necessitate advanced risk mitigation strategies because of the potentially disastrous effects of stockouts, while also expanding this understanding to illustrate how patient safety elements establish particular demands for the implementation of blockchain and AI. The implications reach far beyond simple inventory management seen in other sectors, encompassing the entire framework of technological adoption. This suggests that successful DT in PSCs should prioritise patient safety above all else, rather than focusing solely on efficiency gains.

The study found serious inaccuracies in demand forecasting is currently present, with errors in some markets reaching as high as 300% according to SD1.This finding directly supports the research hypothesis that DT is necessary in PSCs because current SCM procedures are no longer adequate. 82.1% of organisations continue to use Excel spreadsheets for forecasting activities, indicating a significant gap between current technological capabilities and actual implementation within PSCs. The research reveals that despite decades of technological advancement in other sectors, the pharmaceutical industry continues to rely on traditional approaches that can contribute to supply chain vulnerabilities. A fundamental change from reactive to proactive inventory management is possible with AI-powered predictive analytics, which directly addresses how AI can improve RMI strategies.

However, the research also reveals an unexpected finding, the benefits of such technologies can only be realised through comprehensive organisational change management and workforce development initiatives suggesting that technological solutions alone are insufficient to address forecasting inadequacies. One of the surprising and significant conclusions of the study is that there is a conflicting link between the potential of technology and its actual application. All of the interviewees acknowledged the potential for blockchain and AI technology to transform RMI strategies. However, the real implementation of the technology within the sector is limited and dispersed at current. Instead, the research reveals deeper structural challenges within pharmaceutical organisations including integration complexities with legacy systems, regulatory uncertainties, and cultural resistance to change. This unexpected outcome challenges purely technology-focused approaches to enhancing supply chain resilience and suggests that successful DT requires addressing multiple interconnected barriers simultaneously. The findings indicates that technical implementation alone is insufficient and that organisations must also invest in change management, workforce training and cross-functional collaboration mechanisms in order to successfully integrate DT.

6.2 Critical Engagement with Literature and Theoretical Implications

The study advances the theory of SCM by showing how characteristics unique to a given industry can radically alter the applicability of general supply chain concepts. The results challenges prevailing supply chain resilience models by showing that conventional approaches while being useful require significant adjustment when applied in highly regulated industries where product failures can have fatal consequences. The research extends blockchain and AI current literature by providing evidence of implementation challenges within complex regulatory environments, contradicting technology-focused studies that emphasise technical capabilities without addressing organisational and regulatory barriers.

While existing literature often presents blockchain and AI as solutions to supply chain challenges, this research reveals a more complex reality where technological potential does not automatically translate to implementation success. The findings diverge from optimistic technology adoption models by demonstrating that regulatory compliance requirements, organisational culture, and patient safety considerations create unique barriers not adequately addressed in general supply chain literature. The research also challenges assumptions in pharmaceutical supply chain literature that suggest industry conservatism is the primary barrier to innovation. Instead, the findings indicate that cautious approaches to digital transformation represent rational responses to high-stakes operational environments rather than organisational inertia.

7.0 Conclusion

7.1 Research Question Resolution and Key Contributions

This research has addressed the central question of how blockchain technology and AI can enhance RMI strategies in PSCs to improve resilience and regulatory compliance. The study reveals that while these technologies possess substantial potential for enhancement, their successful implementation requires fundamental changes in organisational approach and with regulatory frameworks. The research indicates that risk-benefit analyses relating to the implementation of DT in PSCs are significantly impacted by patient safety considerations, instead of concentrating on traditional efficiency metrics, this calls for the implementation of strategies that highlight the continuity of medication supply over efficiency metrics alone. This raises critical considerations regarding conventional supply chain optimisation approaches and underscores the importance of tailored frameworks for evaluating technological progress within specific industries. This study highlights a significant gap between technological capabilities and actual implementation process, questioning prevailing assumptions regarding the industry readiness for DT.

7.2 Integration with Existing Literature and Theoretical Advancement

The research findings largely support existing literature on pharmaceutical supply chain challenges while providing new insights into the specific barriers preventing technological adoption. The identification of patient safety as the primary driver of inventory decisions aligns with regulatory compliance literature emphasising the unique constraints of pharmaceutical operations, while extending this understanding to demonstrate how these constraints create specific requirements for technological solutions. The research contests the technology adoption literature by demonstrating that technological capabilities alone are inadequate for successful implementation in highly regulated contexts. The findings enhance DT theory by illustrating that regulated industries necessitate fundamentally distinct strategies for technology adoption in contrast to conventional commercial sectors.

7.3 Comprehensive Recommendations for Stakeholders

Pharmaceutical organisations should establish cross-functional DT teams with representatives from supply chain, quality assurance, regulatory affairs, and IT departments. They should be encouraged to implement pilot programs for blockchain track-and-trace capabilities in non-critical product categories and develop AI-powered demand forecasting capabilities with built-in safety margins for critical medications. Comprehensive change management strategies that address cultural opposition to technology adoption are also necessary. Industry leaders should work with regulatory agencies to create clear guidelines for emerging technology applications, invest in digital literacy and advanced analytics workforce development programs and form industry consortiums to share best practices to solve implementation issues. Regulatory agencies should be advised to develop specific guidance documents for blockchain and AI applications in PSCs, create regulatory testing programmes allowing controlled testing of innovative technologies and establish collaborative frameworks for ongoing dialogue between industry and regulatory bodies.

7.4 Future Research Directions

Several critical avenues for future investigation could significantly advance understanding of technology adoption in regulated industries. Longitudinal implementation studies, involving multi-year research tracking the evolution of blockchain and AI adoption in pharmaceutical supply chains, could provide insights into how implementation challenges change over time and identify critical success factors for sustained technological transformation. Quantitative performance analysis, through research measuring the actual performance impacts of technological implementations via controlled studies, could complement the qualitative insights provided by this research and establish evidence-based business cases for technology adoption. Comparative regulatory analysis, investigating different regulatory environments, could illuminate how policy frameworks influence technological adoption rates and identify best practices for regulatory support of innovation. Interdisciplinary integration research, combining supply chain management, information systems, regulatory science, and organisational behaviour perspectives, could provide a more comprehensive understanding of the complex factors influencing technological adoption in regulated industries.

7.5 Final Reflections and Broader Implications

The pharmaceutical industry is at a turning point in its development, current organisational and regulatory frameworks have not kept up with the significant advancements in technological capabilities. The findings of this study indicate that blockchain and AI technologies have the potential to significantly improve PSC resilience and regulatory compliance, however, in order to fully realise this potential technological adoption must be viewed as an organisational transformation process rather than a technical challenge. The findings suggest that successful implementation requires sustained commitment to addressing organisational, regulatory and cultural barriers in tandem, the pharmaceutical industry's main objective to maintain the continuous availability of life-saving medications establishes both the necessity and the structure for effectively managing this technological transformation. The implications also reach beyond the pharmaceutical sector to other heavily regulated industries facing comparable challenges in balancing innovation with safety and compliance requirements. As DT continues to develop in PSCs, the frameworks and insights derived from this research offer essential advice for navigating DT in intricate, regulated contexts where the consequences of failure are intolerably severe. The study concludes that integrating blockchain technology and AI can significantly improve RMI strategies and resilience in PSCs, but realising these advantages requires a fundamental shift from a solely technology focused approach to a more comprehensive transformation strategy. This strategy must address the specific challenges faced by highly regulated industries while also continuously educating employees to maximise the potential of these advanced technologies

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9.0 Appendix

9.1 List of Interview questions

1. Can you tell me about how you got started in pharmaceutical supply chains? and how did you get into your current role?

2. In your experience, how have Risk Mitigation Inventory (RMI) strategies evolved in pharmaceutical supply chains? Can you give an example of a successful approach you've seen implemented?

3. In my research, I have come across a lot about blockchain and AI's potential in the pharmaceutical sector. Have you seen these technologies impact traceability, transparency, or decision-making in your work?

   Part 2: Were there any surprising benefits or challenges?

4. Balancing inventory costs with supply chain resilience presents unique challenge. In your view, what are some effective strategies organisations can use to navigate this balance?

   Part 2: Additionally, how do you see the role of technology evolving in supporting these efforts?

5. Let's talk about regulatory compliance within the sector. What compliance challenges do you think most organisations encounter, and do you believe technological improvements could help to address them?

6. Demand forecasting in pharmaceutical supply chains presents unique challenges due to regulatory requirements, product lifecycles, and patient safety considerations. How do you approach demand forecasting, and what role do you see technology playing in improving forecast accuracy and supply chain decision-making?

7. Looking ahead, how do you see blockchain and AI evolving to aid supply chain resilience and RMI strategies in the next 5-10 years?

8. As we wrap up, from your experience, what is one thing you think pharmaceutical organisations should focus on when trying to improve their supply chain with any form of new technologies?

Back up questions.

1. What initiatives have you used to improve information sharing and collaboration among stakeholders in your supply chain?

2. How have blockchain and AI technologies impacted different stakeholders in your pharmaceutical supply chain, such as manufacturers, distributors, and patients? Can you provide specific examples of positive or negative effects on each group?

9.2 Interview Consent form

How can blockchain and AI improve risk mitigation inventory strategies in pharmaceutical supply chains to aid resilience and regulatory compliance?

<u>Consent to take part in research.</u>

- I……………………………………… voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves a 30–45-minute interview based on blockchain, and Artificial Intelligence ability to improve RMI strategies in pharmaceutical supply chains to aid resilience and regulatory compliance.
- I understand that I will not benefit directly from participating in this research.
- I agree to my interview being audio-recorded.
- I understand that all information I provide for this study will be treated confidentially.
- I understand that in any report on the results of this research, my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I understand that disguised extracts from my interview may be quoted in the student's dissertation and published on the NCI library.
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.
- I understand that signed consent forms and original audio recordings will be retained in a password protected USB only accessible by the student until 5 years after the interview which is retained for the examination's board
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for in a password protected USB only accessible by the student until 5 years after the interview which is retained for the examination's board

- I understand that under freedom of information legislation, I am entitled to access the information I have provided at any time while it is in storage as specified above.

- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Names, degrees, affiliations, and contact details of researchers (and academic supervisors when relevant).

Signature of research participant

Signature of participant Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study.
Signature of researcher Date

Dylan Delamere
X21516039@student.ncirl.ie

NCI
Coláiste Náisiúnta na hÉireann | National College of Ireland

9.3 Human Participants Ethical Review Application Form

All parts of the below form must be completed. However in certain cases where sections are not relevant to the proposed study, clearly mark NA in the box provided.

Part A: Title of Project and Contact Information

Name

Dylan Delamere

Student Number (if applicable)

X21516039

Email

X21516039@student.ncirl.ie

Status:

- Undergraduate ☑
- Postgraduate ☐
- Staff ☐

Title of Research Project

How can blockchain and AI improve risk mitigation inventory strategies in pharmaceutical supply chains to aid resilience and regulatory compliance?

Have you read the NCI Ethical Guidelines for Research with Human Participants?

- Yes ☑
- No ☐

Please indicate any other ethical guidelines or codes of conduct you have consulted

N/A

Has this research been submitted to any other research ethics committee?

- Yes ☐
- No ☑

If yes please provide details, and the outcomes of this process, if applicable:

Is this research supported by any form of research funding?

- Yes ☐
- No. ☑

If yes please provide details, and indicate whether any restrictions exist on the freedom of the researcher to publish the results:

Part B: Research Proposal

Briefly outline the following information (not more than 200 words in any section).

Proposed starting date and duration of project

19th September 2024 – 4th July 2025

The research aims and objectives

This research aims to enhance current techniques of SC RMI by investigating the potential of blockchain technology and artificial intelligence in conjunction with one another to create improved RMI strategies

The rationale for the project

This research proposal aims to investigate the integration of blockchain technology and artificial intelligence (AI) to enhance Risk Mitigation Inventory (RMI) strategies in pharmaceutical supply chains (PSCs). The project addresses critical issues in the pharmaceutical industry, including improving supply chain resilience, enhancing regulatory compliance and traceability, optimising inventory management, and addressing limitations in forecasting. By exploring the combination of blockchain's secure data sharing and AI's predictive analytics capabilities, the research seeks to revolutionise inventory management, potentially reducing costs while maintaining or improving supply chain performance. The research aligns with the current digital transformation in the pharmaceutical industry and seeks to enhance decision-making and responsiveness in pharmaceutical supply chains.

The research design

The methods of data collection

Interviews

The research sample and sample size

5 pax

The nature of any proposed pilot study

Comprehensive review of the 1st and 2nd interview conducted

The methods of data analysis

N/A

Part C: Ethical Risk

Please identify any ethical issues which will arise and how you will address them.

Cannot identify an organisation by name and all interviews will be stored using password protected data

Please indicate any risk of harm or distress to participants.

None

Please indicate how you will address this risk (e.g. debriefing procedures, etc.).

n/a

Do the participants belong to any of the following vulnerable groups?
(Please tick all those involved).

- ☐ Children;
- ☐ The very elderly;
- ☐ People with an intellectual or learning disability
- ☐ Individuals or groups receiving help through the voluntary sector
- ☐ Those in a subordinate position to the researchers such as employees
- ☐ Other groups who might not understand the research and consent process
- ☐ Other vulnerable groups

How will the research participants in this study be selected, approached and recruited?

N/A

What inclusion or exclusion criteria will be used?

N/A

How will participants be informed of the nature of the study and participation?

Consent form

What procedures will be used to document the participants' consent to participate?

Consent form

If vulnerable groups are participating, what special arrangements will be made to deal with issues of informed consent/assent?

N/a

Please include copies of any information letters and consent forms with the application.

Part D: Confidentiality and Data Protection

Please indicate the form in which the data will be collected.

☐ Identified ☐ Potentially Identifiable ☑ De-Identified

What arrangements are in place to ensure that the identity of participants is protected?

Remaining anonymous in the study.

Please indicate any recording devices being used to collect data (e.g. audio/video).

Phone - mp3 / Teams recording

Please describe the procedures for securing specific permission for the use of these recording devices in advance.

Download recording to a secure drive & delete recording from the phone /laptop

Please indicate the form in which the data will be stored.

☐ Identified ☐ Potentially Identifiable ☑ De-Identified

Who will have responsibility for the data generated by the research?

Myself, the researcher

Please describe the procedures of the storage and destruction of data.

Store for up to 5 years. NCI can request data for up to 5 years.

Dissemination and Reporting

Please describe how the participants will be informed of dissemination and reporting (e.g. submission for examination, reporting, publications, presentations)?

Consent form

If any dissemination entails the use of audio, video and/or photographic records (including direct quotes), please describe how participants will be informed of this in advance.

n/a

Part E: Signed Declaration

I confirm that I have read the NCI Ethical Guidelines for Research with Human Participants, and agree to abide by them in conducting this research. I also confirm that the information provided on this form is correct.

Signature of Applicant : Dylan Delamere____________________________________
Date 04/07/2025__________________________

Signature of Supervisor (where appropriate)
____
Date _____________________________

National College of Ireland
Human Participants Ethical Review Exemption Form

All parts of the below form must be completed. However in certain cases where sections are not relevant to the proposed study, clearly mark NA in the box provided.

Part A: Title of Project and Contact Information

Name

Dylan Delamere

Student Number (if applicable)

X21516039

Email

X21516039@student.ncirl.ie

Status:

- Undergraduate ☑
- Postgraduate ☐
- Staff ☐

Title of Research Project

How can the integration of blockchain technology and artificial intelligence enhance Risk Mitigation Inventory strategies in pharmaceutical supply chains to improve resilience and regulatory compliance?

Have you read the NCI Ethical Guidelines for Research with Human Participants?

- Yes ☑
- No ☐

Please indicate any other ethical guidelines or codes of conduct you have consulted

Has this research been submitted to any other research ethics committee?

- Yes ☐
- No. ☑

If yes please provide details, and the outcomes of this process, if applicable:

Is this research supported by any form of research funding?

- Yes ☐
- No ☑

If yes please provide details, and indicate whether any restrictions exist on the freedom of the researcher to publish the results:

Part B: Research Proposal

Briefly outline the following information (not more than 200 words in any section).

Proposed starting date and duration of project

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The research design

n/a

The methods of data collection

n/a

The research sample and sample size

n/a

The nature of any proposed pilot study

n/a

The methods of data analysis

n/a

Part C: Grounds for Exemption

Please indicate the grounds on which you are applying for exemption from ethical review.

N/a

Please confirm that the research does NOT involve any of the following:

- ☐ Vulnerable groups
- ☐ Sensitive topics
- ☐ Risk of psychological or mental distress
- ☐ Risk of physical stress or discomfort
- ☐ Any other risk to participants
- ☐ Use of drugs or invasive procedures (e.g. blood sampling)
- ☐ Deception or withholding information from participants
- ☐ Conflict of interest issues
- ☐ Access to data by individuals/organisations other than the researchers
- ☐ Any other ethical dilemmas

Part D: Signed Declaration

I confirm that I have read the NCI Ethical Guidelines for Research with Human Participants, and agree to abide by them in conducting this research. I also confirm that the information provided on this form is correct.

Signature of Applicant: Dylan Delamere ______________________________
Date 04/07/2025____________________________

Signature of Supervisor (where appropriate)

____

Date ______________________________