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List of Abbreviations

ADHD	Attention Deficit Hyperactivity Disorder
AI	Artificial Intelligence
ANOVA	Analysis of Variance
API	Active Pharmaceutical Ingredient
DAO	Decentralised Autonomous Organisation
CPU	Corporate Pharmaceutical Unit
DHL	Dalsey, Hillblom and Lynn
DPS	Dynamic Purchasing System
EMA	European Medicines Agency
ERP	Enterprise Resource Planning
FMD	Falsified Medicines Directive
GDPR	General Data Protection Regulation
GP	General Practitioner
GmP	Good Manufacturing Practice
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
HTA	Health Technology Assessment
IDA	Industrial Development Authority
IMVO	Irish Medicines Verification Organisation
IoT	Internet of Things
IPHA	Irish Pharmaceutical Healthcare Association

KPI	Key Performance Indicator
MES	Manufacturing Execution System
PLC	Programmable Logic Controller
PPP	Public-Private Partnership
RD&I	Research, Development & Innovation
RFID	Radio-Frequency Identification
SCADA	Supervisory Control and Data Acquisition
SME	Small Medium Enterprises
t-test	Student's t-test
WHO	World Health Organisation

Abstract

The Irish public healthcare system is facing growing challenges due to recurring drug supply shortages, which significantly impact patient care and healthcare operations. This research investigates whether blockchain technology can serve as a viable solution to enhance transparency and data-sharing between pharmaceutical manufacturers and healthcare providers in Ireland, with the ultimate aim of reducing such shortages.

The primary research question explores the feasibility of using blockchain to enable timely and secure sharing of manufacturing and supply chain data across public and private stakeholders. Supporting objectives include identifying current barriers in data access, evaluating blockchain's benefits and technical integration challenges, and gauging stakeholder demand for cross-industry collaboration.

A mixed-methods approach was adopted, combining quantitative survey data with qualitative interviews. Surveys were completed by 45 professionals from healthcare, life sciences, supply chain, and regulatory backgrounds, selected through purposive sampling. The survey gathered perceptions on drug shortages, blockchain awareness, trust in data-sharing, and governance preferences. Data was analysed using descriptive statistics, t-tests, Analysis of Variance, and Chi-square testing. The qualitative phase consisted of in-depth, semi-structured interviews with six subject matter experts across the life sciences and healthcare domains. Thematic analysis was used to extract insights aligned with the study's core objectives.

Findings revealed broad awareness of drug shortages across all sectors, with manufacturing delays, supply chain fragility and quality, and lack of real-time data identified as critical factors. Participants viewed blockchain as a potentially transformative technology, particularly for improving traceability, trust, and data integrity. However, technical barriers, such as integration complexity, data standardisation, and regulatory compliance, were seen as significant adoption hurdles. Upstream processes, such as provision of quality raw material, and downstream processes, such as Ireland's market size and drug approval practices, were highlighted and present significant challenges to drug manufacturing organisations. A consistent theme across interviews was the need for secure, permissioned data environments and proof-of-concept pilots to build trust and validate impact.

The study concludes that blockchain holds promise in alleviating drug shortages through enhanced data-sharing and visibility, but successful adoption will depend on cross-sector

collaboration, regulatory alignment, and demonstrable pilot outcomes. Recommendations include the development of national governance frameworks, implementation of limited-scale blockchain pilots, and the creation of funding models that support public-private partnerships to ensure system-wide scalability and sustainability.

1. INTRODUCTION

1.1 Research Topic

The Irish public healthcare system faces persistent drug shortages that disrupt patient care and strain operational resources. This research investigates whether blockchain technology can facilitate timely, transparent sharing of manufacturing and supply chain data between pharmaceutical manufacturers and healthcare providers, with the goal of mitigating such shortages.

The central research question examines the feasibility of using blockchain to support cross-industry data integration. Objectives include identifying current barriers to data access, evaluating blockchain's benefits and technical challenges, and assessing stakeholder interest in real-time, secure data-sharing.

A mixed-methods approach was employed. Quantitative surveys were completed by 45 professionals from healthcare, life sciences, logistics, and regulatory sectors to capture their perceptions of drug shortages, trust in blockchain, and governance preferences. Analysis involved descriptive statistics, t-tests, Analysis Of Variance (ANOVA), and Chi-square tests. Qualitative data was gathered through nine in-depth interviews with subject matter experts, analysed thematically to explore operational realities, perceived benefits, and adoption challenges.

Findings highlight a range of contributing factors to drug shortages, including manufacturing delays, supply chain fragmentation, and a lack of integration between upstream (raw materials, production) and downstream (distribution, hospitals) actors. While many stakeholders recognised blockchain's potential to improve traceability and trust, there was limited awareness of its applications beyond cryptocurrency. Integration complexity, data privacy concerns, and regulatory compliance were also cited as barriers to adoption.

The study concludes that blockchain offers significant promise in improving pharmaceutical supply chain resilience. However, successful implementation requires strong governance, proof-of-concept pilots, and stakeholder education to bridge technical and cultural gaps. Key recommendations include launching targeted blockchain pilots, creating national

governance frameworks, and supporting cross-sector collaboration through public-private funding models and awareness-building initiatives.

1.2 Research Title

Use of Blockchain Technology in reducing drug supply shortages in the Irish public healthcare system through cross-industry data-sharing of pharmaceutical manufacturing and supply chain data.

1.3 Research Aim

The key aim of this research paper is to examine if Blockchain Technology can be used to facilitate timely and transparent sharing of manufacturing and supply chain data to reduce shortages in supply of life-changing drugs to patients within Ireland's public Health Service Executive (HSE) system. This will be viewed specifically from the perspective of integrating private Life Science organisations with the Irish public healthcare system, to trace all steps involved in the production and distribution of drug products to healthcare providers. The evaluation of Blockchain will be limited to the identification and assessment of challenges in data integration and will not include a case study or full technical feasibility study of the technology itself.

1.4 Research Objectives

1. Identify current challenges with supply chain data access for high demand drugs in Ireland's healthcare system.
2. Evaluate the benefits of Blockchain in sharing of data related to critical drugs across manufacturing and healthcare organisations.
3. Identify and assess the technical challenges of integrating data with Blockchain.
4. Determine qualitative demand for sharing of manufacturing & supply chain data (seller) and drug administration data (buyer).
5. Determine the feasibility of adopting Blockchain technology to reduce drug supply shortages.

2. LITERATURE REVIEW

2.1 Introduction

Drug shortages have become a significant concern in Ireland, with wide-ranging implications for patient care, healthcare providers, and the overall healthcare system. The World Health Organisation (WHO) identifies medicine shortages as a global issue, and Ireland is no exception, facing increasing disruptions in medicine availability over recent years. This has highlighted the need for systemic changes to mitigate the risks and impacts of such shortages (HPRA, 2023).

The Health Products Regulatory Authority (HPRA) defines a medicine shortage as occurring when "the supply of a medicinal product is inadequate to meet the needs of patients." This definition emphasises the critical role of patient needs and the complexity of addressing shortages (HPRA, 2023). For example, shortages of oncology drugs during chemotherapy regimens can lead to treatment delays with severe consequences for patients (HPRA, 2023).

The issue has been increasingly publicised in recent years, with healthcare professionals across Ireland expressing their concerns. Pharmacist Kathy Maher shared, "I dread the winter in case we have similar shortage in antibiotics as we experienced nearly two years ago", where she further associated “difficulties with shortages of treatment for Attention Deficit Hyperactivity Disorder (ADHD), with manufacturing delays” (O’Regan, E. 2023). In 2023, over 200 medicines, including antibiotics, vaccines, and cardiovascular treatments, were reported to be in short supply in Ireland, significantly disrupting public health initiatives and patient care protocols (Griffin, N. 2023; Graham, B. 2023.).

The impact of medicine shortages is multifaceted. For patients, the lack of availability of essential medicines can lead to deteriorating health outcomes, particularly for vulnerable populations such as cancer patients and individuals with chronic conditions (HPRA, 2023). For healthcare providers, the burden includes increased administrative efforts to manage shortages, sourcing alternatives, and adjusting treatment plans, which further strain an already pressured system (Horgan, S. 2023).

Geographically, rural areas face heightened challenges, with pharmacies in these regions often reporting severe disruptions in supply chains. This exacerbates inequities in healthcare

access across the country (O'Regan, E. 2023; Kirby, J. 2024). Irish Pharmacy Union President Dermot Twomey stated, "there is a certain amount coming into the country but is divided out or effectively rationed between pharmacies" (Horgan, S. 2023).

The underlying causes of drug shortages are varied and interconnected:

1. **Manufacturing Challenges**: Interruptions in production due to raw material shortages, quality control issues, and reliance on single-source manufacturing are major contributors (HPRA, 2023).
2. **Supply Chain Vulnerabilities**: Factors such as logistical delays, inadequate stockholding by suppliers, and distribution inefficiencies further compound the problem (HSE, 2024). Without better forecasting tools, supply chains will remain reactive instead of proactive. In addition, Sandra Gannon, Azure Chief Executive, states that "Weaknesses in the supply chain alone highlights the imperative of revisiting the pricing framework for medicines to protect supply of stock and protect Irish patients." (O'Regan, E. 2023)
3. **Economic and Regulatory Issues**: Regulatory compliance, limited market competition, and pricing negotiations also play critical roles in limiting the availability of medicines (HSE, 2024). Sandra Gannon, Azure Chief Executive highlighted, "…single supply source and are reimbursed at such low prices that other suppliers are unwilling to enter such a small market" (Griffin, N. 2023).

   Oliver O'Connor, Chief Executive of Irish Pharmaceutical Healthcare Association (IPHA), highlighted "that of the cancer medicines that have been authorised by the European Medicines Agency (EMA), since 2020, only one in four are now available in Ireland" (Bowers, F. 2025). These delays in market approvals by the Irish regulators have been described as taking approximately 468 days on average to approve for Irish patients to access the medicines and takes 644 days from when the EMA has authorised market access. The small market size of Ireland in comparison to its EU counterparts often result in Life Science companies prioritising market launch in other, more lucrative, markets. This backed up in comments from Professor Michael Barry, Clinical Director of the National Centre for Pharmacoeconomics who highlights countries such as Germany, Italy and Spain gain earlier access where margins are more attractive, with delays in applying for

market access in Ireland a key contributor to delays in making drugs available (Bowers, F. 2025).

Notable examples of drugs impacted by shortages include: Antibiotics, Vaccines, Statins, Neurological Medicines, Oncology Drugs, and Diabetes which have been widely reported issues across Ireland's public health system. Most notably, issues relating to pharmaceutical manufacturing and supply chain have been cited as some of the reasons causing delays in drug supply.

To tackle these challenges, the HPRA emphasises a multi-stakeholder approach involving manufacturers, wholesalers, healthcare providers, and policymakers. Preventative strategies include enhanced stockholding requirements, improved supply chain transparency, and robust forecasting tools to identify potential shortages before they occur (HPRA, 2023; HSE 2024).

Efforts to streamline procurement processes, including the use of a Dynamic Purchasing System (DPS), have shown promise in ensuring compliance with EU regulations and fostering competitive pricing (HSE 2024). Additionally, early notifications of potential shortages and collaborative solutions to sourcing alternatives are critical components of the HPRA's framework (HPRA, 2023).

Life Science companies have also been urged to improve transparency. As one industry report highlighted, "From industry information received by the HPRA, we know that over 60pc relate to delays or breakdowns during manufacturing…" (O'Regan, E. 2024).

In conclusion, drug shortages in Ireland are a multifaceted issue with profound consequences for public health and system efficiency. Coordinated efforts, systemic improvements, and proactive strategies are essential to mitigate the impacts and ensure consistent access to essential medicines.

2.2 Secondary Research Aim

This literature review provides insights from a comprehensive collection of scholarly and industry sources to explore the role of blockchain technology in transforming supply chains between the Life Science and Healthcare sectors. The review examines its potential to address inefficiencies, enhance transparency, and improve governance while overcoming

challenges related to data sharing, interoperability, and adoption barriers. By drawing on case studies, frameworks, and empirical research, this section highlights blockchain's potential to integrate public and private healthcare systems securely and sustainably.

The integration of blockchain technology into pharmaceutical supply chains has the potential to revolutionise operations by addressing persistent challenges such as inefficiencies, lack of transparency, and poor governance. Blockchain offers a decentralised, immutable, and secure ledger system that ensures real-time traceability and accountability. These attributes make it particularly suitable for industries requiring high levels of trust, for example healthcare and pharmaceuticals (Yen-Ting et al., 2022).

However, while the benefits are numerous, achieving successful adoption is not without challenges. Technical limitations, high implementation costs, and the need for cross-sector collaboration often slows progress (Sodhi et al., 2022). Furthermore, concerns surrounding data privacy, interoperability, and compliance with complex regulatory frameworks, such as the General Data Protection Regulation (GDPR), must be addressed for blockchain to deliver its promised benefits (Matulevičius et al., 2022).

This review explores blockchain's application in life science and healthcare supply chains, focusing on several key themes.

2.3 Secondary Research Findings

To address the research objectives and explore how Blockchain can reduce drug supply shortages by facilitating cross-industry data-sharing, a review of relevant literature was conducted, focusing on the following key areas:

1. Data Sharing and Interoperability Challenges
2. Blockchain's Role in Enhancing Transparency and Traceability
3. Addressing Supply Chain Challenges
4. Healthcare Specific Supply Chains
5. Public-Private Partnerships and Governance

2.3.1 Data Sharing and Interoperability Challenges

The healthcare and life science sectors face significant hurdles when it comes to data

sharing. These include disparate data silos, regulatory inconsistencies, and competing stakeholder interests. The WHO has highlighted that inefficient data-sharing mechanisms often result in delayed decision-making and increased operational costs, particularly during global crises such as the COVID-19 pandemic (Zhang et al., 2022).

Traditional systems rely heavily on centralised databases that are prone to security breaches, loss of data integrity, and restricted accessibility. Blockchain, by contrast, provides a decentralised architecture that ensures all stakeholders have access to the same verified data in real time, reducing risks associated with single points of failure (Hodapp and Hanelt, 2022). This is especially important in pharmaceutical supply chains, where accurate and timely information about drug production, distribution, and storage is critical.

Interoperability between disparate systems is another major challenge. Healthcare systems are notoriously siloed, with different business units and hospital groups using incompatible technologies and data standards. Hodapp and Hanelt (2022) argue that achieving true interoperability requires standardised protocols, which blockchain can facilitate. For instance, hyper-connected ecosystems that support modular architectures, allow organisations to customise blockchain solutions while maintaining interoperability.

Sun (2024) demonstrates that integrating semantic ontologies with blockchain can significantly improve data exchange efficiency by ensuring that disparate systems, with "most synthetic algorithms use semantic ontology-based forward and backward chain construction", that speak the same language. Similarly, Griffiths et al. (2023) highlight the application of semantic frameworks in agricultural supply chains, suggesting a transferable model for pharmaceutical systems. These semantic approaches are not just theoretical; real-world implementations, such as MediLedger, have shown promise in enabling seamless data exchange between life science manufacturers and distributors (Healthcare Purchasing News (2017).

While blockchain can enhance data sharing, it also introduces ethical and regulatory complexities. Andanda and Mlotshwa (2024) stress that ethical-legal frameworks must evolve alongside technology to ensure compliance with cross-border data-sharing requirements. Blockchain's immutability, while a strength, can conflict with GDPR's right to rectification and erasure. To address this, hybrid solutions combining on-chain and off-chain storage have been proposed previously. For example, Matulevičius et al. (2022) argue

that these systems balance the need for immutability with privacy obligations by storing sensitive data off-chain and only referencing it on-chain. As many life science organisations are structured across different geographies, where individual drug components are added in different countries during the process, balancing the regulatory requirements throughout the production process is key.

Another limitation lies in blockchain's reliance on consensus mechanisms, which can slow down transaction speeds as networks scale. Blockchain's scalability challenges disproportionately affect high-volume industries, namely life sciences, where real-time data processing is essential. Solutions such as sharding and layer-2 scaling have been proposed but remain in experimental stages, requiring further research.

Life science supply chains involve multiple stakeholders, each using different systems and platforms. Sun (2024) observes that while blockchain interoperability frameworks aim to address this so that "interoperability makes accurate consolidation and processing of data from several sources possible", achieving widespread adoption requires substantial collaboration among industry players.

Furthermore, blockchain's integration with emerging technologies, such as Artificial Intelligence (AI) and Internet of Things (IoT) devices, offers new possibilities. Srivenkateswaran et al. (2024) demonstrate how hybrid frameworks combining blockchain with IoT can enhance real-time data collection and sharing, while AI-powered analytics can identify and address inefficiencies within processes. Though more research is needed in this area, complimentary emerging technologies may reduce the complexity of implementations and adoption, incentivising life science organisations to participate.

2.3.2 Blockchain's Role in Enhancing Transparency and Traceability

Transparency ensures that all stakeholders in the supply chain, from manufacturers to healthcare procurement, have access to accurate, verifiable data. By recording every transaction on an immutable ledger, blockchain eliminates information asymmetry, fostering trust across the network (Yen-Ting et al., 2022). For instance, MediLedger's blockchain platform has been instrumental in improving traceability by enabling life science companies and pharmacies to verify the origin of drug products in the supply chain while keeping commercial data sensitive (Healthcare Purchasing News (2017).

Blockchain's traceability capabilities are particularly valuable in ensuring the integrity of high-value or commercially sensitive products, such as vaccines and biologics. Zimmerman (2006) emphasises the importance of utilising technologies such as Radio-Frequency Identification (RFID) and IoT sensors to monitor product conditions, such as temperature and humidity, throughout transit. These technologies, when integrated with blockchain, could enable real-time tracking and automatic alerts in case of deviations, ensuring compliance with stringent storage requirements.

Smart contracts also play a crucial role in enhancing traceability. Vargas and Mira da Silva (2023) note that "blockchain provides security for medical data, and the smart contracts are used for anyone or anything that wants access, performing a function of accessing control, that detects, tracks, and controls the data sharing". For example, a smart contract can automatically verify that a shipment meets regulatory standards before releasing payment, streamlining the overall process. Zhu (2024) complements this by highlighting how blockchain-enabled incentive mechanisms encourage active participation from all stakeholders, ensuring that the "best transaction partner is selected from numerous information providers to achieve the optimal transaction result".

Transparency also introduces ethical dilemmas. For instance, Schwabe et al. (2019) warn that "sharing a data platform frequently leads to conflicts between private partners", an example of moral hazard. Life science organisations must balance the need for transparency with the need to protect proprietary data, a challenge that blockchain-based zero-knowledge proof systems can help address. These systems allow companies to verify the authenticity of their claims without revealing sensitive information.

Security vulnerabilities, particularly in permissioned networks, also pose challenges. Hodapp and Hanelt (2022) argue that the perception of security in blockchain networks often overlooks risks associated with node collusion and smart contract exploits. Hybrid encryption models that integrate advanced cryptographic techniques, such as Elliptic Curve Cryptography, provide promising solutions but increase implementation complexity (Srivenkateswaran et al., 2024).

Despite its advantages, blockchain's transparency capabilities are not without limitations. One significant challenge is data integrity. While blockchain can ensure that data is not manipulated once uploaded, it cannot verify the accuracy of the data at the point of entry.

Yen-Ting et al. (2022) examine the virtual-physical link between digital records and what is happening on the ground, noting that "at the source, often a remote location like a mine, forest, or ocean, how is it possible to ensure that the data are correctly entered into blockchain,". The importance of robust data verification mechanisms to ensure there is a "... clear way to know if the data entered into the blockchain was accurate at the source." This highlights the already well-known issue of relying on the quality of data being entered into a system (i.e. bad data in, bad data out).

Another challenge lies in achieving industry-wide adoption. Transparency benefits are fully realised when all stakeholders participate in the blockchain network, yet achieving consensus among diverse entities with competing interests can be difficult (Goldsby and Hanisch, 2022).

Scaling blockchain's transparency capabilities requires a multi-pronged approach that includes technological innovation, stakeholder engagement, and regulatory support. Srivenkateswaran et al. (2024) demonstrate that integrating blockchain with hybrid encryption frameworks can enhance both transparency and data security, addressing concerns about over-transparency.

In addition, blockchain's ability to support Decentralised Autonomous Organisations (DAO) presents a unique opportunity for scaling transparency. DAOs operate through smart contracts, ensuring that all decisions and transactions are transparent and verifiable (Rikken et al., 2019). Vargas and Mira da Silva (2023) highlight that "The use of smart contracts on supply chains can guarantee data provenance, makes the use of intermediaries unnecessary, and provides a secure, immutable history of transactions to all stakeholders".

2.3.3 Addressing Supply Chain Challenges

The COVID-19 pandemic surfaced the numerous vulnerabilities inherent in global pharmaceutical supply chains. Zhang et al. (2022) described the compromising of timely delivery of critical medical supplies, where "issues with decentralisation for inventory management created problems with the efficiency and effectiveness of PPE management". These disruptions highlighted a lack of resilience in existing supply chain infrastructures, where dependencies on disparate systems and limited real-time visibility often exacerbated delays.

Blockchain technology offers solutions to mitigate such vulnerabilities by decentralising data management and enhancing transparency across supply chains. Healthcare Purchasing News (2017) notes that many products "require perfect inventory management and that's not the way the world works so there's going to be a lot of exception handling — we believe that the blockchain can automate a lot of those." The ability to quickly identify and address bottlenecks is crucial during crises, where real-time decision-making can significantly impact public health outcomes.

A key advantage of blockchain lies in its decentralised architecture, which reduces the risks associated with single points of failure. Unlike traditional systems, where data breaches or system outages can force down-time in operations, Blockchain networks distribute data across multiple nodes. Srivenkateswaran et al (2024) highlights that federated hybrid networks are "resilient against multiple types of attacks, including physical capture, eavesdropping, password guessing, spoofing, forgery, replay, impersonation, de-synchronisation, man-in-the-middle, privileged insider, denial of service, stolen smart device, and known session-specific temporary information attacks".

Blockchain also addresses inefficiencies in supply chain operations by streamlining workflows and reducing reliance on non-value add activities. Smart contracts, for instance, automate processes such as inventory management, order validation, and payment settlements. Vargas and Mira da Silva (2023) argue that "10% of deaths in the USA may be caused by medical errors" and that "Thousands of lives could be saved annually if smart contracts could be utilised to improve patient medical record data, drug supply chains, and medical collaboration". The use of smart contracts is seen as a mechanism to eliminate manual errors and reduce processing times, enabling faster and more accurate supply chain operations.

Zhu (2024) compliments this, suggesting that "Blockchain technology offers advantages such as traceability, decentralisation, and timestamps, allowing precise recording of participants' actions." In addition, blockchain's ability to provide real-time visibility across supply chains improves coordination among stakeholders. Kagoya et al. (2020) emphasise that "grass-root integration of real-time automated pharmaceutical intelligence systems to collect, consolidate, monitor, and report" pharmaceutical information systems data can enable seamless collaboration between manufacturers, distributors, and healthcare providers, reducing delays and improving service delivery. This is particularly beneficial in

over-burdened public hospital settings, where inefficiencies in supply chain management can have life-threatening patient outcomes.

Blockchain's potential to integrate with predictive analytics further enhances its value in mitigating supply chain risks. Islam et al. (2022) introduce ontology-based frameworks that utilise machine learning to predict vulnerabilities in supply chains. These frameworks analyse historical data to identify patterns and potential disruptions, allowing stakeholders to take proactive measures. For example, predictive models can forecast demand surges during flu seasons or pandemics, enabling manufacturers to adjust production accordingly. For this to be operationalised in an Irish public health setting, bi-directional flow of data would be required to optimise the forecasting capabilities.

Despite its potential, implementing blockchain to address supply chain fragility is not without challenges. One significant challenge is scalability. Srivenkateswaran et al. (2024) observe that "scalability is essential to accommodate the growing volume of healthcare data generated daily", with blockchain networks sometimes associated with struggling to handle the high transaction volumes required in global supply chains, leading to delays and increased costs. Choosing the right solution and "incorporating specialised hardware accelerators and efficient data management strategies will handle intensive computational tasks and large data volumes", reducing the impact of scalability challenges.

Another challenge lies in achieving stakeholder buy-in. Goldsby and Hanisch (2022) argue that resistance to change among supply chain participants can hinder blockchain adoption, particularly in industries where legacy systems are deeply entrenched. Giving the size and complexity of the Irish public healthcare system, the HSE, and its legacy systems, stakeholder willingness is essential to successful integration of Blockchain. Building trust among stakeholders is also essential, as blockchain's success depends on active participation from all parties. Public-Private Partnerships (PPP) can play a pivotal role in overcoming these barriers by providing the necessary regulatory support and financial incentives to encourage adoption (Schwabe et al., 2019).

Additionally, blockchain's role in enabling collaborative ecosystems cannot be understated. DiVito et al. (2020) argue that cross-sector collaborations facilitated by blockchain improve coordination and resource allocation, making supply chains more resilient to disruptions. For example, collaborative blockchain platforms can pool resources during crises, ensuring

that critical supplies reach areas of greatest need.

2.3.4 Healthcare Specific Supply Chains

Specialised healthcare supply chains, such as those handling biologics, gene therapies, and vaccines, present unique challenges that blockchain technology is well-suited to address. These supply chains often involve strict regulatory compliance, temperature-sensitive products, and complex logistics networks. Blockchain's ability to provide a transparent, immutable record of transactions and conditions at each stage offers significant advantages in these contexts.

Zimmerman (2006) highlights that "The industry needs to address all technology solutions, from secure product packaging to tracking techniques such as tags, holograms, and ultimately radio frequency identification. All of these begin with the manufacturer, require wholesaler involvement and rely on the pharmacy." For temperature-sensitive products such as vaccines, IoT-enabled sensors integrated with blockchain can provide real-time data on storage conditions, ensuring compliance with regulatory standards. Srivenkateswaran et al. (2024) demonstrate that blockchain-enabled systems reduce the risk of temperature excursions by automating alerts and compliance checks.

The production and distribution of gene therapies are becoming increasingly in demand in recent years and are expected to grow exponentially. They are also among the most complex healthcare supply chains, involving highly individualised treatments and stringent handling requirements. Matulevičius et al. (2022) argue that blockchain-enabled ontological frameworks enhance security and data integrity in managing healthcare data, which is critical for maintaining the quality of gene therapies. These frameworks enable end-to-end traceability, ensuring that every step is securely recorded —from patient sample collection to therapy delivery for example.

In addition, blockchain's role in facilitating collaboration among stakeholders in gene therapy supply chains cannot be understated. Sun (2024) notes that blockchain fosters trust and collaboration by creating a shared platform where stakeholders can access verified data in real-time. This is particularly important in cross-sector supply chains, where coordination is key to ensuring timely delivery and maintaining product integrity. DiVito et al. (2020) emphasise that "that value is not created in isolation but rather by organisations working

together through partnerships and agreements". This is particularly important for ensuring equitable access to life-saving treatments facing reduced supply.

While blockchain's applications in specialised healthcare supply chains are promising, they are not without challenges. One major barrier is the high cost of implementing blockchain-based solutions, particularly for small and medium-sized enterprises. Yen-Ting et al. (2022) note that the financial and technical requirements of blockchain systems often exclude smaller stakeholders, potentially widening inequalities within supply chains. Though one can argue this would not impact large organisations such as the HSE, or multi-national life science organisations, their size and complexities can expect to increase the cost of implementations.

2.3.5 Public-Private Partnerships and Governance

Governance is one of the most critical factors influencing blockchain adoption in life science supply chains. Effective governance structures are necessary to foster trust, ensure accountability, and facilitate collaboration among diverse stakeholders. DiVito et al. (2020) argue that "through governance mechanisms, managers or leaders make decisions about how available resources are directed, coordinated, and allocated toward desired outcomes.", which is pivotal to the success of blockchain initiatives.

Despite the benefits of blockchain, data sharing within the life science sector is not without its challenges. Critics argue that blockchain's decentralised nature can introduce governance challenges, particularly in ensuring accountability and equitable participation among stakeholders. Tafuro et al. (2023) argue that while public sector entities tend to focus on accessibility and equitability in service provision, private sector organisations are more attuned to the bottom line, making "organisational arrangements and governance strategy typical of a PPP, it is difficult, if not impossible, to reasonably realise common benefits." Additionally, Hodapp and Hanelt (2022) caution that achieving interoperability is more of a socio-technical issue than a purely technical one, requiring substantial organisational changes and stakeholder buy-in. This point is echoed by Sodhi et al. (2022), who note that early stage blockchain projects often fail to deliver on their promises due to inflated expectations and poor integration strategies.

Governance frameworks also often struggle with power imbalances, as resource-rich private

entities may dominate decision-making processes, sidelining less agile stakeholders. Goldsby and Hanisch (2022) warn that robust governance structures that balance power dynamics and prioritise shared objectives are needed to address this issue, reducing the risk of moral hazard.

Cross-border supply chains further complicate compliance efforts due to regulatory fragmentation. Saberi et al. (2019) stress the need for harmonising regulations across jurisdictions to ensure that blockchain systems can operate effectively on a global scale. PPPs can help establish harmonised frameworks that align regulatory requirements across regions, reducing barriers to adoption.

One study identifies the entanglement between application and infrastructure governance as a significant hurdle, where “governance on the application layer are closely entangled with the governance on the infrastructure level and cannot be separated” (Rikken et al., 2019). Furthermore, GDPR compliance introduces complexities, due to blockchain’s principle of immutable data contrasted with data deletion requirements. Blockchain’s immutability often conflicts with data protection regulations, such as GDPR, which grant individuals the right to request data erasure. The Olympus: A GDPR Compliant Blockchain System study suggests that off-chain storage and distributed governance frameworks are practical solutions to these challenges. Gonçalves et al. (2024) propose hybrid blockchain solutions that store sensitive data off-chain while maintaining references on-chain, enabling compliance without compromising blockchain’s immutability.

Another study proposes federated learning and differential privacy to enhance security and data-sharing efficiency in blockchain applications (Javed et al., 2023). In this study, the authors reviewed “existing and next-generation methodologies for federated, secure, and privacy-preserving” and an architecture “which makes use of differential privacy and secure multiparty computing”.

Dynamic governance models provide a potential solution. These models allow for flexible decision-making and adaptation to evolving needs, as well as providing flexible financing models. Cruz (2013) cites the example of the Portuguese government adopting PPP models for “dealing with financial constraints while having to increase health service spending, cost overruns in infrastructure investments and a political directive to increase private sector involvement in the delivery of public services”. Examples such as these are of significant

importance to public policy makers in Ireland as country size and challenges are comparable in nature.

Additionally, DAOs built on blockchain can provide a unique governance model for supply chains. DAOs enable stakeholders to collectively make decisions and manage resources transparently, reducing power in-balances and enhancing trust. Rikken et al. (2019) highlight that DAOs democratise decision-making in supply chains, ensuring that all stakeholders have a voice in governance.

Public agencies play a crucial role in governance frameworks. Schwabe et al. (2019) highlight that public entities act as "guarantors of data quality" and trust, ensuring that blockchain systems align with public health goals. Their involvement is particularly important in cross-border supply chains, where varying regulations and standards can create barriers to adoption. For instance, government agencies can help establish standardised protocols for data sharing and compliance, providing a foundation for consistent implementation across jurisdictions. Schwabe et al. (2019) argue that public-private partnerships "play an important role in interorganisational processes as a supplier of data, a source of trust, a guarantor of data quality, a user of data, and an incentive for making goods public", as they can align incentives and establish shared governance structures.

Blockchain technology enhances PPP effectiveness by providing a transparent and accountable platform for collaboration. For instance, smart contracts automate compliance checks, ensuring adherence to pre-agreed terms. Vargas and Mira da Silva (2023) note that smart contracts "makes it possible to eliminate the ambiguity of contracts in general, increase efficiency in their execution, and substantially reduce the risk of default between the parties."

Governance and PPPs are critical to the successful adoption of blockchain in pharmaceutical supply chains. These frameworks address technical, organisational, and regulatory challenges while promoting collaboration between public and private stakeholders. Blockchain adoption requires inclusive governance structures, dynamic collaboration models, and equitable decision-making to align the interests of diverse stakeholders. Ethical concerns, including data sovereignty and privacy, must also be addressed. PPPs must establish clear guidelines on data ownership and access to ensure ethical compliance (Andanda and Mlotshwa, 2024).

PPPs bridge the gap between public health priorities and private sector innovation, creating collaborative frameworks for blockchain adoption. Andanda and Mlotshwa (2024) emphasise that "collaborative efforts from communities, researchers, governments, the healthcare industry, and international organisations to ensure fair and responsible cross-border data sharing" is imperative to addressing ethical and legal challenges. PPPs enable resource pooling, allowing stakeholders to develop scalable blockchain solutions while addressing financial and technical barriers. Each of these aspects are key to developing an ecosystem in Ireland, bridging the gaps between public sector healthcare needs and private sector life science manufacturing and supply chain operations.

2.4 Conclusion

While blockchain presents significant potential, its implementation is not without challenges. One major critique is its scalability. Srivenkateswaran et al. (2024) acknowledge that current blockchain systems struggle to handle high transaction volumes efficiently. This limitation poses risks for large-scale adoption in global pharmaceutical supply chains.

Another limitation is the high energy consumption associated with blockchain technologies. Zhu (2024) notes that current consensus mechanisms are environmentally unsustainable, urging a shift toward more energy-efficient algorithms such as Proof-of-Stake. Additionally, Hodapp and Hanelt (2022) warn that fragmented governance structures often lead to inconsistent regulatory adherence, which can hinder cross-border collaboration.

Sodhi et al. (2022) also argue that early stage blockchain implementations often fail to meet inflated expectations, leading to scepticism among stakeholders. Addressing these limitations requires a focus on education, incremental adoption, and transparent communication to manage expectations effectively.

Overcoming these barriers requires a multifaceted approach that addresses technical, regulatory, financial, and organisational challenges. One promising strategy is the development of scalable blockchain solutions. Layer-2 scaling technologies and consensus algorithms such as Proof-of-Stake can significantly improve blockchain's scalability without compromising security. Additionally, integrating blockchain with complementary technologies such as AI and IoT can enhance its functionality and cost-effectiveness.

Regulatory challenges can be addressed through harmonised frameworks and collaborative governance models. Goldsby and Hanisch (2022) emphasise that public-private partnerships are essential for aligning blockchain implementation with regulatory requirements while ensuring that industry needs are met. These partnerships can also facilitate knowledge sharing and the establishment of industry standards, reducing uncertainty and building trust among stakeholders.

Furthermore, Gonçalves et al. (2024) propose hybrid blockchain solutions that store sensitive data off-chain while maintaining references on-chain, enabling compliance without compromising blockchain's immutability to address concerns with GDPR regulations.

Rikken et al. (2019) outline the importance of DAOs and smart contracts in combating governance issues stemming from traditional, centralised structures that are not adapted to Blockchain solutions.

Financial barriers can be mitigated through innovative funding mechanisms such as consortium-based models. Schwabe et al. (2019) propose that blockchain consortia, where multiple organisations share the costs and benefits of blockchain infrastructure, can lower the financial burden on individual participants. Similarly, government subsidies and grants can incentivise blockchain adoption, particularly for Small Medium Enterprises (SME).

This literature review underscores blockchain's transformative potential in pharmaceutical supply chains. By addressing inefficiencies, enhancing transparency, and fostering collaboration, blockchain offers a robust solution to pressing challenges in healthcare and logistics. However, its adoption requires overcoming governance, technical, and operational barriers. Future research should focus on developing scalable frameworks that meet regulations and are governed effectively to maximise its impact on supply chain optimisation, in particular as relates to addressing drug shortages.

3. METHODOLOGY

This research aims to investigate the role of Blockchain technology in reducing drug supply shortages in the Irish public healthcare system by enabling cross-industry data-sharing between pharmaceutical manufacturers and healthcare providers. The study will focus on identifying current challenges, evaluating Blockchain's benefits, assessing technical integration challenges, understanding data-sharing demands, and determining Blockchain's feasibility for addressing drug shortages. The findings will offer insights into the potential of Blockchain for creating a more transparent, efficient supply chain for critical drugs.

3.1 Research Methodology and Approach

To inform the primary data collection, comprehensive secondary research will be conducted to analyse the regulatory landscape of Blockchain and data-sharing in Ireland's healthcare sector. This analysis will focus on understanding GDPR requirements, data governance protocols, and existing regulations governing cross-industry data-sharing, with particular attention to drug traceability and patient data protection. The insights gained will guide the formulation of interview and survey questions and ensure regulatory compliance considerations are addressed prior to engaging with participants.

3.2 Conceptual Framework

In order to effectively research the use of Blockchain as a method to reducing drug shortages in the Irish Public Healthcare system, a number of key influencing factors and themes will be examined. Diagram 1 below, outlines the key factors that will impact this research. Firstly, in order to accurately assess the benefits of using Blockchain, the scale and specificities of the problem must first be researched. This will be conducted primarily through primary and secondary research, focusing on Irish Public Healthcare actors to determine the current state.

The next phase of understanding comes with analysing the potential Life Science sector challenges in integration of manufacturing and supply chain data with Blockchain, along with validating commercial interest for these organisations to do so.

A cross-sector examination, through primary research, will evaluate the willingness of stakeholders in both the Irish Public Healthcare sector and a sample set of Life Science organisations, in entering data-sharing arrangements with third party organisations.

Finally, the results of researching these key factors of influence will inform this research on whether integrating and sharing manufacturing and supply chain data between the two sectors will adequately address the problems highlighted with drug shortages.

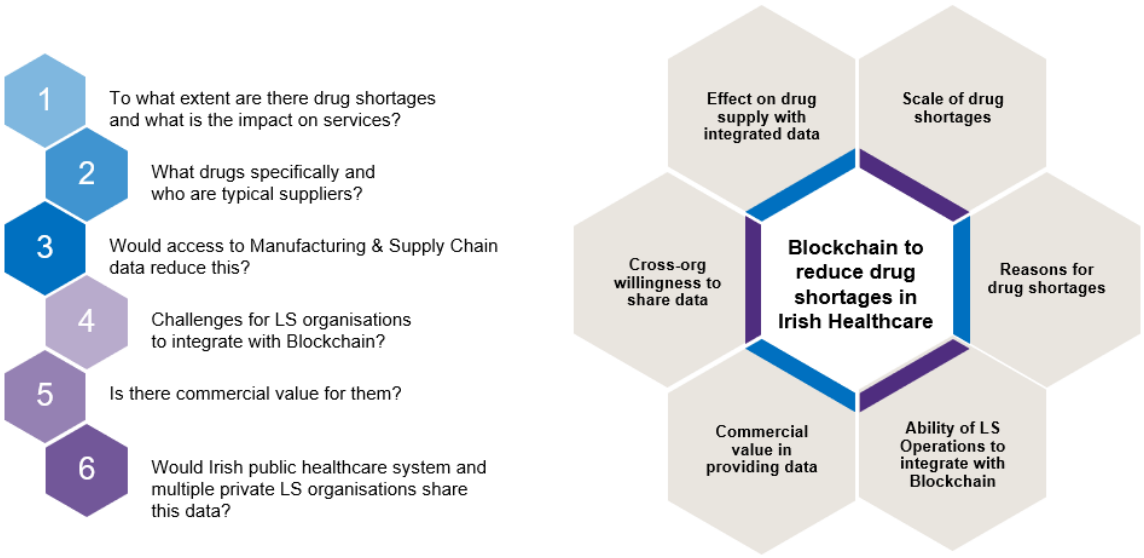

Figure 1: Overview of key factors influencing primary and secondary research for this paper

3.3 Secondary Research and Regulatory Analysis

The study will adopt an interpretivist philosophy, which prioritises the perspectives of stakeholders involved in healthcare and pharmaceutical manufacturing and supply chains. An inductive approach will guide data collection and analysis, allowing themes and theories to emerge directly from the quantitative data gathered through surveys and qualitative data from subject matter experts. The research will utilise a mixed-methods design, with a focus on the intersection of quantitative and qualitative. Quantitative insights from surveys, such as the use of Likert and Linear numeric scales to evaluate sentiment, opinions and perceptions, will be leveraged. Insights gathered from the surveys will be aggregated and provided to participants taking part in interviews, to gain further qualitative analysis on the key themes. This design will support a comprehensive understanding of various stakeholder challenges and perceptions "to ensure that data already rich in quality was also thick in quantity, two key ingredients for data saturation (Dibley, 2011)".

3.3.1 Data Collection Methods

1. **Quantitative Data through Surveys**

Surveys will be conducted to assess the challenges of cross-industry data-sharing and measure attitudes toward Blockchain's role in improving drug supply chains and public healthcare perceptions of same. These surveys will target participants with backgrounds in healthcare and life sciences, aiming to capture their perspectives on current problems, challenges, trust in Blockchain, and willingness to allow restricted data-sharing across 3rd parties.

- **Survey Design**: Questions will be crafted to gather quantitative data and insights, addressing issues such as trust in Blockchain and perceived data privacy risks, the perceived value of sharing drug-related data across sectors, and the relationship between public and private organisations.
- **Participant Selection**: Surveys participants will be selected from manufacturing and supply chain areas of Life Science organisations; identified through contacts and networks of senior colleagues in the current workplace (Grant Thornton) and industry body groups, as well as professional consultants with expertise in this area.
- Representatives from public healthcare and pharmacy areas, those with healthcare professional backgrounds, as well as professional consultants with expertise in this area will be selected to participate. A number of selected participants will have had direct operational experience in key regulatory bodies in Ireland, including the HSE, HPRA, and the NDMP.

2. **Qualitative Data through Stakeholder Interviews**

Key insights will be gathered through in-depth interviews with subject matter experts from both the life sciences and healthcare sectors, where they will build upon the analysis of the quantitative surveys. Interviews will be provided with aggregated points of view from the survey population to build out a further understanding of the themes. The focus will be on understanding the existing challenges in supply chain data access for high-demand drugs, the technical considerations for Blockchain integration, and stakeholder perspectives on Blockchain's feasibility in addressing drug shortages.

- **Participants**: Subject matter experts from healthcare, life science and industry body backgrounds will be selected for the interview process. Participants from different disciplines within and agnostic of those sectors

will provide broader insights and viewpoints, such as those with technology, strategy, operations and pharmacy.

- **Interview Topics**: Interviews will explore current supply chain challenges, the perceived value of data-sharing, technical challenges related to Blockchain integration, and stakeholder views on the feasibility and potential benefits of Blockchain. This is in addition to exploratory questions related to viewpoints gathered from survey participants.
- **Preparation**: To enhance efficiency, interview question packs will be shared with participants in advance, covering topics relevant to each stakeholder's area of expertise. Question packs will be tailored to the individual stakeholder based on their area of expertise, so as to explore specific topics in more detail. The questions will be designed in a manner that mitigates the risk of introducing bias and open-ended questions will be utilised to allow participants to fully explore topics they deem relevant to the research. Interviews will be held remotely to accommodate a wider participant pool which will be based across Ireland and in the US.

3.3.2 Data Analysis and Thematic Categorisation

The collected data will be analysed to identify key themes relevant to each research objective. For interviews, themes will include:

- Current challenges with supply chain data access
- Technical barriers to Blockchain integration
- Value and feasibility of Blockchain in reducing drug shortages
- Stakeholder perspectives on regulatory and compliance requirements
- Trust in Blockchain for data privacy and security

For surveys, thematic analysis will focus on:

- Perception of drug shortages as an issue in Ireland and its impact
- Perceived causes of drug shortages in Ireland
- Trust in data-sharing technology, especially in terms of privacy and cybersecurity
- Cross-industry data-sharing initiatives and where responsibility lies
- Perceived value in sharing drug-related data across the healthcare and pharmaceutical sectors

The final analysis will combine qualitative insights from stakeholder interviews with quantitative survey results, presenting key findings in this paper with metrics and visualisations to provide further understanding. The paper will provide insights into the feasibility of Blockchain Technology in reducing drug shortages in the Irish public healthcare system and optimising the supply chains of Life Science organisations, through digital transformation.

An Example Survey Questionnaire was prepared during the Methodology development phase of this research project before being finalised in the Primary Research phase, and can be found in Appendix E. This example questionnaire formed the basis for identifying the appropriate data points for analysis before being finalised ahead of primary research gathering. The survey questionnaire was piloted with select participants before publishing to the wider population.

3.4 Ethical Considerations

This research was conducted in accordance with established ethical standards and institute guidelines to ensure the integrity of the study and the protection of all participants involved. The research involved non-vulnerable adults and did not deal with sensitive personal or clinical information.

All interview participants were provided with a detailed Participant Information Letter outlining the study's purpose, methodology, voluntary nature of participation, and how their data would be used and protected. Prior to participation, individuals were required to sign an Informed Consent Form, confirming their understanding and agreement to participate. Participants were informed of their right to withdraw at any time and could request that their data be excluded from the research within two weeks of participation.

To ensure confidentiality, all participant names referenced in the research are pseudonyms. Any potentially identifying details were removed or masked during data transcription and analysis, including data pertaining to employer information or commercially sensitive data. This approach preserved participant anonymity and complied with the expectations outlined in the consent documentation.

Transcribed interview data, where consent was granted, were securely stored and used solely for the purposes of transcription and thematic analysis. Signed consent forms and transcribed interview data will be retained in a secure, access-controlled environment for a

period of two years following the completion of this research, in line with data retention guidance.

The study did not involve the collection of clinical or patient data, and no commercial data subject to confidentiality agreements was disclosed. Participants were made aware that if any information suggesting a risk of harm to themselves or others emerged during the study, the researcher might be ethically obligated to report this to the relevant authorities.

In addition to the qualitative interviews, an anonymous online survey was distributed to professionals experienced in the relevant industries. No personally identifiable information was collected, and respondents were not required to provide names, email addresses, employer or commercially sensitive data. Participation was entirely voluntary, and the survey platform is protected by secured from unauthorised access. This approach ensured complete anonymity and encouraged open responses while adhering to ethical standards of data privacy, security and informed consent.

Ethical approval for this research was obtained in advance and a signed copy of the Ethics Declaration Form can be found in Appendix F of this research paper.

4. PRIMARY RESEARCH FINDINGS AND ANALYSIS

This phase of the research project investigated the potential for Blockchain technology to reduce drug supply shortages within the Irish public healthcare system through cross-industry data-sharing between pharmaceutical manufacturers and healthcare providers, using primary research data gathering techniques.

To explore the challenges and benefits, as well as evaluate Blockchain's feasibility as a solution, both qualitative and quantitative data was collected.

4.1 Survey Analysis Approach

The survey analysis conducted for this study forms a core component of the mixed-methods design, providing foundational quantitative insights that inform and complement the subsequent qualitative interviews. In line with the interpretivist philosophy and inductive approach adopted for this research, the survey was carefully designed to capture perceptions, attitudes, and experiential knowledge from professionals across the Irish healthcare and life sciences sectors. Questions were structured around key thematic domains including supply chain transparency, technological familiarity, data governance, and stakeholder trust in Blockchain technology; each of which directly aligns with the core research objectives. Respondents were segmented by industry sector, organisational engagement, and years of experience to facilitate both descriptive analysis and comparative statistical testing.

The data was evaluated using descriptive analytics, both visual interpretation and inferential statistical techniques including Chi-square analysis, T-tests, and ANOVA; to identify any statistically significant relationships or perceptual variances across stakeholder groups. Likert scale responses were analysed to enable comparative evaluation of sentiment, while categorical responses, such as preferred governance and funding models, were aggregated to reveal cross-sectoral trends. Descriptive analytics were used to lay the foundation of the population dataset, highlight key indicators, and provide an aggregated view of the respondents. The use of ANOVA and T-tests aimed to test for differences in perceptions based on professional experience or awareness of drug shortages, while Chi-square tests examined associations between sectoral background and attitudinal variables.

This approach allowed for a robust analysis of the survey data, providing clarity on stakeholder views and the potential alignment, or misalignment, between healthcare, and life science and technology focused professionals. In doing so, it also helped to surface points of contention, commercial hesitations, or trust gaps that may influence the feasibility of Blockchain adoption in this context. These insights laid the groundwork for the subsequent interview phase, where complex themes could be explored in greater depth and individual perspectives could be probed beyond the limitations of fixed-response formats. Ultimately, the quantitative survey analysis served not only as a standalone data source but also as a tool to guide the qualitative strand of the research, ensuring a comprehensive and multi-dimensional exploration of Blockchain's role in mitigating drug shortages within Ireland's public healthcare system.

4.1.1 Survey Results and Analysis

To evaluate the feasibility of Blockchain technology in reducing drug shortages through enhanced supply chain transparency, a structured survey was issued among professionals in healthcare, life sciences, technology and related industries. A total of 45 valid responses were collected, covering a broad range of sectors and experience levels. The findings provide valuable insights into stakeholder perceptions, levels of technological readiness, and willingness to engage in Blockchain-enabled data-sharing initiatives.

4.1.2 Sector Representation and Background

Respondents to the survey represented a sample population with a diverse cross-section of industries, including notable participation from the healthcare (clinical and administrative), pharmaceutical manufacturing, logistics, and professional services sectors. Years of experience ranged broadly even across early-career (0–2 years), mid-career (3–10 years), and senior professionals (>10 years). This distribution provided a balanced interpretation of stakeholder perspectives across varying levels of exposure, experience and strategic responsibility. Figures 1 and 2, below, provide a summarised view of the demographics associated with the sample population, including professional backgrounds and years of experience.

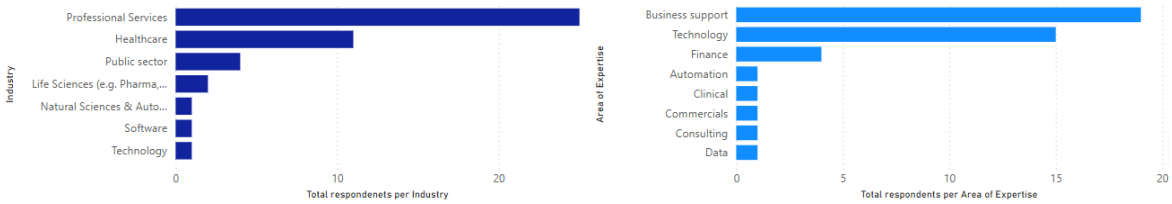

Figure 2: Summary of professional backgrounds

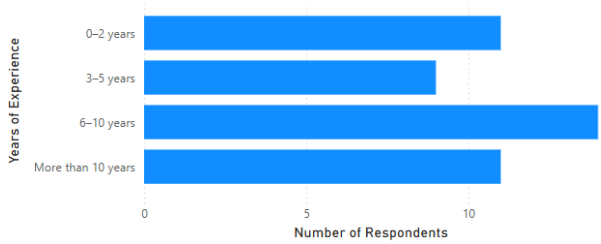

Figure 3: Overview of sector experience levels

4.1.3 Likert Scale Analysis

To quantitatively assess stakeholder attitudes, the survey included a set of Likert-style questions capturing agreement levels and familiarity with key topics. These covered areas such as Blockchain trust, transparency, procurement practices, regulatory understanding, and data-sharing across the healthcare and pharmaceutical sectors. Responses were numerically encoded, with a maximum value of 5 and minimum of zero, and analysed to extract correlations and variations.

The highest scoring item was: “The availability of transparent, real-time supply chain data would influence healthcare procurement decisions” with a mean score of 4.27 and a standard deviation of 0.62, indicating strong agreement and a relatively unified perspective among respondents. This reinforces a central hypothesis of this research: that transparent, timely information is not just a technological enhancement, but a factor that can influence operational decisions in healthcare procurement and incentivise private life science organisations.

Similarly, high mean scores were observed for the statement: “Prioritising procurement from pharmaceutical companies that provide full transparency via Blockchain, should be done, even at a slightly higher cost” with a mean score of 3.84. This suggests moderate to strong support for Blockchain-enabled transparency, even when it entails cost implications. This is an important factor in evaluating the feasibility of adoption within budget-conscious

public healthcare systems, such as in Ireland.

Familiarity questions related to Blockchain technology, such as knowledge of real-world applications and technical implementation, yielded slightly lower scores on average. This indicates a knowledge gap in practical deployment among respondents, which may influence perceptions of feasibility or lead to hesitation despite theoretical support. It should be noted that familiarity with practical Blockchain applications varied across the participant backgrounds and industry experiences. With 25 participants indicating that they were either Familiar or Very Familiar with the technology, versus 20 participants who were either Somewhat Familiar or Not Familiar, there was lack of definitive correlations in terms of responses to other questions, which may have impacted the analysis and warrants further research.

Standard deviation values were generally low to moderate, suggesting a general degree of consensus across the surveyed population. Where variability was higher (standard deviation > 0.8), this typically corresponded to topics where either technological exposure or professional background may have varied substantially, such as regulatory compliance knowledge or third-party data-sharing mechanisms.

Overall, the Likert analysis reveals several key trends:

- There is broad support for data transparency in supply chain decision making;
- Stakeholders are open to Blockchain adoption, particularly where it can demonstrably improve procurement and reduce shortages; and
- However, there is some divergence in technical familiarity, which could hinder early-stage adoption without accompanying education or implementation support.

These insights are invaluable for linking survey results with interview findings, and for identifying potential friction points in the operationalisation of Blockchain technology in the Irish healthcare ecosystem.

4.1.4 Ranked Barriers to Blockchain Adoption

To understand perceived barriers to Blockchain adoption in the Irish healthcare and life sciences sectors, respondents were asked to rank six key concerns from most to least important. The analysis revealed a clear prioritisation of challenges. Complexity of integration emerged as the most significant barrier, achieving the highest average score (6.0), suggesting that respondents view technical and infrastructural alignment with existing

systems as the most significant hurdle. This was followed closely by cost of implementation (5.0), indicating budgetary pressures within both public and private organisations, and a general unease to the upfront investment required for transformative technologies.

Data security risks ranked third, with an average score of 4.0, indicating that while cybersecurity is an important concern, it is not perceived as the most preventative factor. Interestingly, lack of industry adoption was ranked fourth (3.0), suggesting that the current absence of widespread use may hinder trust and momentum but is not itself a root cause of resistance. Public perception, often associated with concerns around data misuse or transparency, was ranked as the least significant concern (2.0), implying that professionals see internal operational and economic barriers as more critical than external or reputational issues. Table 1, below, outlines the results of the ranked scoring of barriers to Blockchain adoption.

Barriers	Total Score	Average Score
Complexity of integration	270	6
Cost of implementation	225	5
Data security risks	180	4
Lack of industry adoption	135	3
Public perception	90	2
Regulatory and compliance challenges	45	1

Table 1: Barriers to Blockchain adoption in order of priority (6 = higher, 1 = lower)

These results suggest that any future Blockchain strategy should prioritise integration pathways and cost mitigation strategies, potentially through proof of concept and pilot initiatives, while continuing to address security and trust-building as secondary enablers rather than primary inhibitors. It must be noted however, that while the style of question gave the respondents the opportunities to rank the key barriers, lower scores do not explicitly indicate that respondents are not concerned by these areas, more that they perceive other barriers to be of more priority or significance.

4.1.5 Governance and Funding Preferences

Survey respondents were asked to identify their preferred funding model for a national Blockchain-enabled supply chain system. Public funding (via government or HSE initiatives) emerged as the most commonly preferred model, particularly among healthcare professionals. However, a substantial cohort from the life sciences sector expressed support

for private sector led models, highlighting the industry's commercial agility, progressive nature and innovation capital. A consortium-based approach, while not dominant, was also proposed, suggesting interest in hybrid governance models to share risk and accountability. Figures 3 and 4, provide statistical insights into the sample population viewpoints on governance and funding responsibilities.

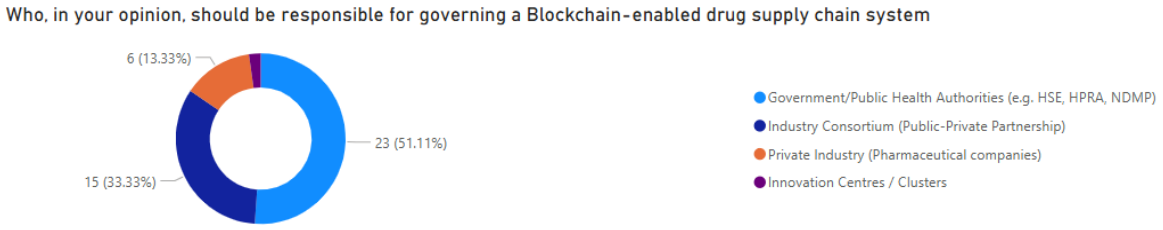

Figure 4: Blockchain governance model

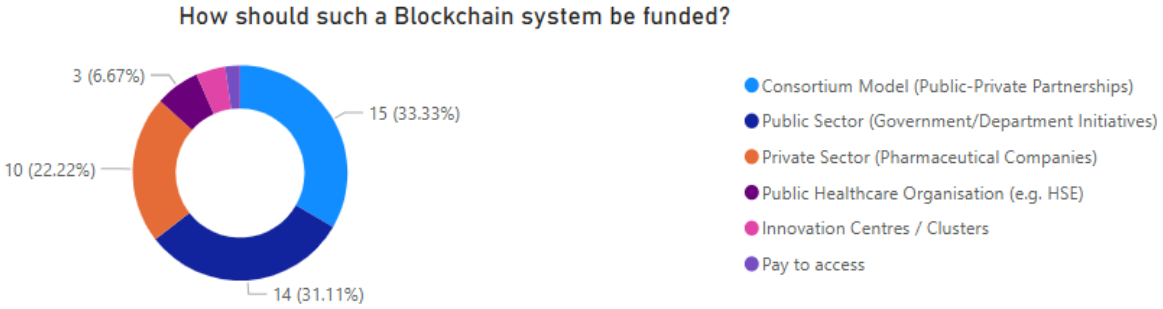

Figure 5: Blockchain funding model

Overall, the variance of responses reflects a fundamental overlap between public sector trust and private sector efficiency, suggesting the need for multi-stakeholder governance frameworks in future implementations. These variations and correlations between industry background and response, serve as a basis for further probing of subject matter experts in the qualitative interview phase.

4.1.6 Influence of Real-Time Supply Chain Data

Respondents overwhelmingly agreed that the availability of transparent, real-time supply chain data should influence procurement decisions. This sentiment was evident across many variables, such as industry background, experience and the awareness of drug shortages in Ireland. This suggests that real-time data visibility is seen as a credible mitigation tool in managing disruptions or inventory inefficiencies.

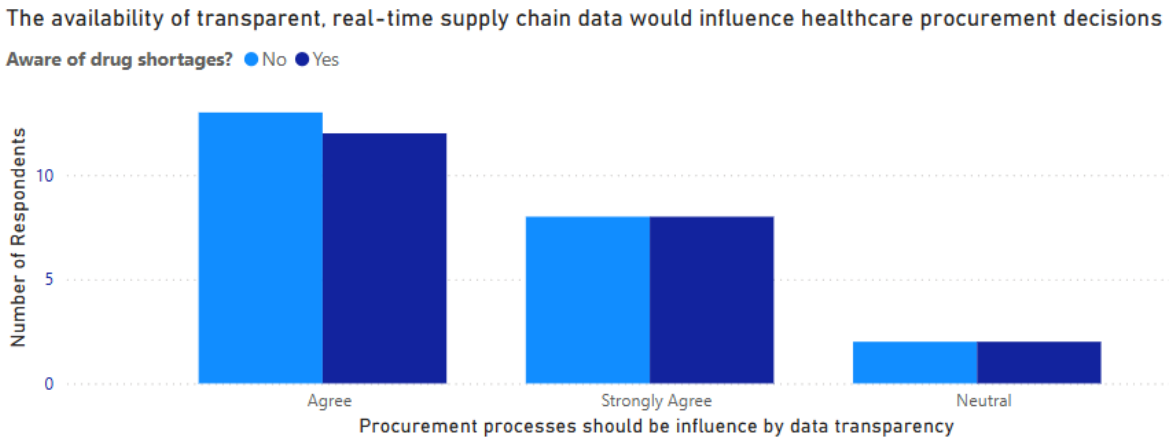

Figure 6: Perception of Real-Time Data Influence on Procurement

In addition to the perceived value that real-time data in procurement decisions, the majority of respondents highlighted their support for favouring data-transparent companies, even it results in slightly higher costs. Though not significantly, there was a higher percentage of respondents in favour of prioritising procurement practises despite increased costs, from those who have an awareness of drug shortages in Ireland. This correlates to those with experience in operational settings where existing problems could be viewed as more of a priority, with real-time data seen as a necessary solution, suggesting that transparency is not just a technical component but a commercially acceptable trade-off against the backdrop of current issues.

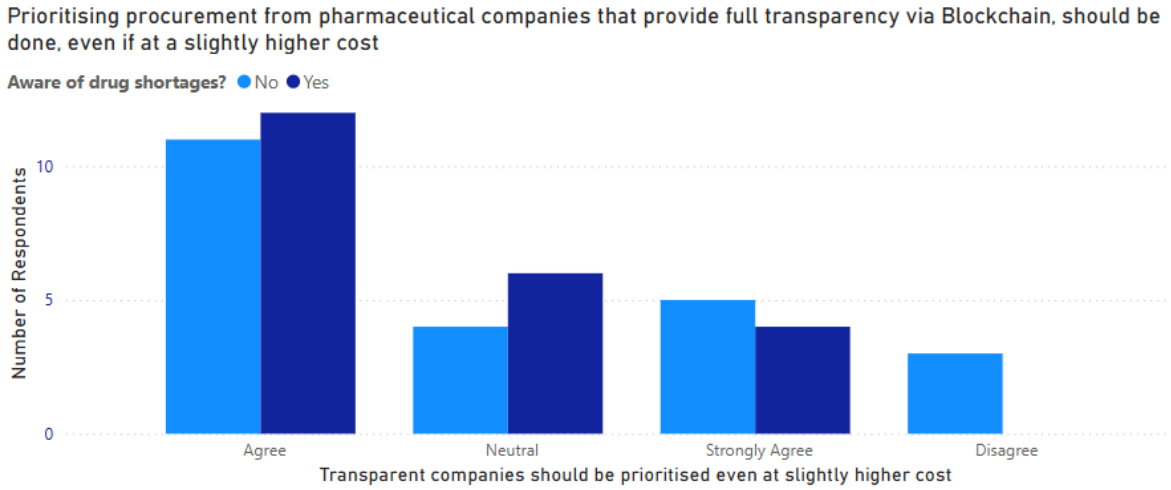

Figure 7: Perception of favouring procurement for transparent companies, despite cost

Interestingly, though those who were aware of drug shortages were slightly more willing to accept higher costs for transparency, a t-test comparing the two groups revealed insufficient statistical power to draw firm conclusions (likely due to the small population data set for each grouping of respondents and variations in years of experience).

In terms of correlations between professional backgrounds and awareness of drug shortages, while sentiment leaned heavily positive, a Chi-square test examining the relationship between industry background and awareness of drug shortages ($\chi^2 = 5.61$, $p = 0.47$) showed no statistically significant association. This suggests that awareness of shortages is widely recognised, irrespective of professional background.

4.1.7 Familiarity with Blockchain and Regulatory Contexts

In terms of technical and regulatory experience, respondents reported a varied range of familiarity with Blockchain, particularly in relation to real-world applications, data privacy, and healthcare-specific use cases. While some life sciences professionals demonstrated strong technical experience, others, especially those from public health or support functions, showed gaps in understanding.

This variation of knowledge and insights across the different sectors and backgrounds suggest a critical role for cross-industry education and regulatory clarity, if Blockchain is to gain widespread adoption across both public and private stakeholders.

4.1.8 Statistical Summary of Key Relationships

Chi-Square: Test	Metric	Result
Sector x Awareness of Drug Shortages	$\chi^2 = 5.61$, $p = 0.47$	Not statistically significant; awareness levels are consistent across sector types.
Organisation Type × Awareness of Drug Shortages	$\chi^2 = 8.31$ $p = 0.31$	Not statistically significant; awareness levels are consistent across org types.
Experience x Awareness of Drug Shortages	$\chi^2 = 7.96$ $p = 0.047$	Statistically significant relationship between years of experience and awareness of drug shortages ($p < 0.05$).

Table 2: Statistical summary of key relationships in the data

While statistical significance was not reached in the inferential tests concerning industry / background and awareness of drug shortages, the analysis of the data strongly aligns with thematic expectations that Blockchain-enabled transparency is perceived as both valuable and feasible across the industries. Testing for relationships between the years of experience of respondents and their awareness of drug shortages in the Irish healthcare system showed statistically significant relationship ($p < 0.05$).

The analysis showed that less experienced professionals (e.g. 0–2 years) were less likely to be aware of drug shortages. More experienced professionals (particularly those with 10+

years) showed higher awareness, likely due to extended exposure to procurement cycles, professional experiences, or previous global supply chain / economic crises.

This insight supports the hypothesis that domain expertise enhances contextual awareness, which may impact on how stakeholders perceive the urgency of solutions analogous to Blockchain.

Although t-test and ANOVA test analysis was completed, aside from statistics outlined above, no clear and conclusive relationships were found that either support or reject the hypothesis. This is reflective of the range and diversification of respondents as well as the niche subject matter expertise involved.

4.1.9 Conclusion of Survey Results Analysis

The survey results provide empirical support for the hypothesis that Blockchain can enhance the resilience and responsiveness of drug supply chains through transparent, real-time data-sharing. Respondents from both public and private domains recognise the value of improved visibility and data-sharing mechanisms, although there remains uncertainty regarding governance models and funding responsibilities. Moreover, while enthusiasm exists, variations in technical and regulatory familiarity indicate the need for continued stakeholder engagement, education, and alignment across industry lines. These results served as a springboard into the qualitative interview phase, where deeper insights into integration challenges, governance, awareness and cross-sector collaboration could be explored in more detail.

4.2 Qualitative Interview Analysis

In this phase of the research, primary qualitative data was gathered through in-depth semi-structured interviews with subject matter experts from across the life sciences, healthcare and technology sectors. These included professionals with experience in pharmaceutical manufacturing, regulation, pharmacy practice, digital transformation, and healthcare consulting. The interview questions were informed by insights from the earlier survey analysis and was designed to explore key themes such as data access, operational barriers, governance considerations, and stakeholder perspectives on Blockchain adoption.

This chapter presents the results of that qualitative analysis. Using a thematic approach, the interview data was analysed and categorised to highlight recurring issues, emerging

patterns, and contrasting viewpoints, all mapped against the core research objectives, which are outlined below:

Research Objectives:

1. Identify current challenges with supply chain data access for high demand drugs in Ireland's healthcare system;
2. Evaluate the benefits of Blockchain in sharing of data related to critical drugs across manufacturing and healthcare organisations;
3. Identify and assess the technical challenges of integrating data with Blockchain;
4. Determine qualitative demand for sharing of manufacturing & supply chain data; and
5. Determine the feasibility of adopting Blockchain technology to reduce drug supply shortages.

Thematic analysis was conducted based on the data gathered during the interview phase, to reflect the practical challenges and opportunities identified by stakeholders, providing a grounded perspective on the role Blockchain could play in strengthening Ireland's pharmaceutical supply chain resilience. The analysis was structured into five main categories, aligned with the objective of the research. Within each category, a total of nine themes emerged and are set out in this chapter.

4.2.1 Current Challenges in Drug Supply and Data Access

Theme 1.1: Supply Chain Disruptions and Quality

An unanimous view emerged around the fragility of the pharmaceutical supply chain in Ireland. Participants such as Laura and Olivia, pharmacists by trade and qualification, were explicit in stating that the issue of drug shortages, though present for a number of years, has been exacerbated in recent years due to Brexit and COVID-19.

Participants Chloe, Laura, and Olivia emphasised that global supply shocks disproportionately impact smaller markets, for instance Ireland. Olivia observed the increase in over-the-counter and chronic medication shortages, while Sarah highlighted the demand for increasing supply of weight loss, ADHD and blood pressure medicines.

Participants also confirmed that the HPRA, who is the regulator overseeing drug supply and compliance in Ireland, maintains a list of the shortages. However, Chloe was keen to point

out that even though the required timeframe for companies to notify the HPRA of potential shortages was 30 days, in his experience the average timeframe was 12 days. This was supported by views from Olivia, Sarah and Laura.

Chloe and Jane noted that lean inventory models and heavy dependence on imported Active Pharmaceutical Ingredients (API), leave the system vulnerable. They cited examples whereby the supply of critical API raw materials sourced from India and China were restricted, particularly during COVID-19. This high dependency, in their experience, creates a domino effect right through the entire supply chain and production processes. Jane pointed to numerous proven incidents whereby this dependency was exploited, as counterfeit drugs entered the market seemingly to take advantage of demand. Counterfeits, as well as cheaply made materials, cause quality issues within the downstream manufacturing processes, which are often not linked back to the source quality issues. With manufacturing delays and issues often highlighted, both Jane and Chloe agree that the issue in quality often occurs much further back the supply chain, where raw materials are sourced.

Theme 1.2 Market Size Limitations and Approvals

Across all interviews - regardless of whether backgrounds related to pharmacy, life sciences or healthcare - Ireland's small market size was cited as a reason for de-prioritisation by pharmaceutical companies. Ireland's small market size was highlighted as a structural limitation. This de-prioritisation leads to delays in drug availability, especially during global crises such as COVID-19 or Brexit. Chloe, Jane and Sarah each indicated instances of stockpiling behaviour in the market, where large volumes of drug are produced, stored and distributed from Ireland to other countries where demand and value per unit is higher, despite shortages in Ireland.

Chloe also noted instances of parallel trading, the definition of which involves buying genuine goods (often branded products) from a market where they are cheaper and selling them in a different market where the price is higher. Sarah emphasised the variations between public and private health systems, whereby countries operating private healthcare systems can often pay higher values to the manufacturers for the same drugs sold into public systems. With life science companies in the private sector increasingly focused on commercialisation and margins, this results further in the de-prioritisation of the Irish market.

Laura adds to this by saying that, in his opinion, reimbursement times are more streamlined

in other countries presenting a similar barrier to prioritisation of the Irish market, 'HSE's Corporate Pharmaceutical Unit (CPU) aim to have a reimbursement decision within 45 days but this is very rarely achieved leading to prolonged delays for pharmaceutical companies in getting their products onto the market'.

Olivia and Jane also strongly suggested that the path to market approval for the sale of drugs in Ireland is too slow, and acts as a barrier for life science companies to sell to the Irish market. Olivia highlighted her attendance at numerous IPHA events where market approval delays were voiced as serious concerns, yet resolutions have not been forthcoming. She indicated that the market approval process 'is not fit for purpose' and compounding delays in supply of medicines.

There was consensus across the participants that a supply chain solution based on Blockchain technology would ideally need to be considered EU wide if not broader, given the market size of Ireland.

Jane offered a previous example where a solution to Irish market limitations was examined in the past, which looked at group purchasing arrangements. In this example, Irish stakeholders sought to coordinate with countries in the Benelux region to negotiate group or bulk purchasing arrangements with the private sector. However, it is not known at this time what barriers or obstacles were identified that has resulted in the scheme moving forward.

Theme 1.3: Fragmented Data Systems and Interoperability Failures

Emily and Chloe highlighted poor interoperability between Enterprise Resource Planning (ERP) systems and a lack of standardised terminology. Data silos within and across life sciences and healthcare organisations limit real-time visibility, contributing to uncoordinated responses during shortages. Chloe described how partner sites struggle to integrate batch data, creating ripple effects when quality deviations occur early in the supply chain. He referenced the complexity of sharing metadata under EU and US regulatory acts and noted that interoperability challenges exist even within single organisations. Many life science organisations, according to Chloe, will have sister sites and inter-linked production processes and supply chain, that are interwoven in theory, but do not have sufficient data-sharing mechanisms in place.

Emily expanded on this by pointing out that inconsistent business terms and lack of shared language across hospital and manufacturer systems significantly hamper integration, and

that without accurate, accessible data, anomalies go unnoticed until disruptions have already occurred. This lack of standardised terminology, protocols and interoperability occurs at almost every level of the supply chain. From suppliers to distributors, one local manufacturing floor system to another, one inter-company site to another, and manufactures to customers; there is a lack of common data models and sharing mechanisms throughout.

4.2.2 Technical and Operational Challenges of Blockchain Integration

Theme 2.1: Standardisation and Cost Barriers

Emily and Jane warned of Blockchain's inefficiencies, including high energy use and infrastructural requirements. Emily noted metadata integration complexities, with regulators requiring detailed datasets across systems. Blockchain, while promising, must evolve to meet industry efficiency demands. Chloe referenced the US Data Security Act and EU serialisation requirements as examples where standardisation efforts already strain organisations. He also pointed out that a significant issue is the reluctance of life science companies to provide data in real-time due to the absence of secure, interoperable platforms.

Emily added that Blockchain could only work at scale if it offers both operational and regulatory efficiency. He emphasised that current validation models are outdated and costly, and while Blockchain could streamline data integrity checks, it must first align with regulatory expectations to replace existing legacy systems. He did however note that some progress has been made in recent decades in respect of the validation models. Prior to the turn of the millennium, every single aspect of new systems, data or process changes needed to independently verified. This has since moved towards a risk-based approach. In Emily's view, significantly more progress must be made to adapt to evolving technologies, particularly as it relates to data. Emily outlined how today; to validate an integrated data solution, each movement of data must be validated throughout the lifecycle. From sensor level to Programmable Logic Controller (PLC), PLC to Supervisory Control and Data Acquisition (SCADA), SCADA to Manufacturing Execution System (MES), and MES to ERP. This creates significant overheads, burdens, and disincentivises change. The current validation model 'costs the industry billions of dollars every year' and requires fundamental change from the regulators.

Theme 2.2: Commercial Sensitivity and Data Security

All participants were in agreement, that the primary concern and requirement of a

Blockchain solution, is to ensure that commercially sensitive proprietary data is kept private. This is of particular importance to private for-profit life science manufacturers. Laura and Sarah emphasised that real-time manufacturing and supply chain data are commercially sensitive. Companies are reluctant to expose operational weaknesses or oversupply, which could be exploited by competitors or impact negotiations with buyers. Sarah noted that revealing data such as stock levels could allow purchasers to leverage pricing power, if there is an awareness of oversupply in a particular drug. He also highlighted, along with Sarah and Jane, that knowledge of locations with significant inventory of high value products could attract criminal activity.

Sarah stressed that the immutability of Blockchain could make companies wary, particularly if a data breach or non-compliance incident were permanently recorded on-chain. Emily echoed these concerns, highlighting that competitive pressures in the pharmaceutical sector make organisations extremely cautious about data-sharing. However, several participants noted that a Blockchain solution that limits access to only relevant data and incorporates robust encryption and governance could mitigate these concerns. Chloe suggested that stakeholders would require complete confidence that they retain ownership over their contributed data, with no risk of exposure to third parties without consent.

4.2.3 Blockchain's Feasibility and Value Proposition

Theme 3.1: Traceability and Trust Benefits

Emily and Chloe articulated Blockchain's potential to enhance traceability and integrity in batch records—vital for regulatory compliance and patient safety. Emily stated that in pharmaceutical manufacturing, "you do two things: you produce the drug, and you create the record of making that drug." He emphasised that without validated records, a product is unsellable, and Blockchain offers a tamper-proof solution for managing this critical documentation. Chloe pointed to international examples of proactive inventory control as replicable use cases, such as a Swedish system that tracked national antibiotic stockpiles and helped with reimbursement. He also highlighted how real-time visibility into national inventory could reveal undisclosed supplies, ultimately enhancing availability and enabling more strategic allocation. Blockchain, by centralising and standardising this data, could significantly reduce medicine shortages and enhance public health outcomes.

There was a consensus across all participants that public awareness of Blockchain is significantly lacking, as well for those within industry. All participants associated

Blockchain mostly with cryptocurrency and finance. Olivia and Sarah were particularly cautious about trusting the technology with sensitive data, with Olivia stating that she 'would not trust my own personal patient records with Blockchain'. Though each of the participants could see the large benefits and future that Blockchain can bring, public perception, comfort levels and trust would be a barrier to wider adoption in the industry.

Theme 3.2: Proof-of-Concept is Critical

Despite conceptual support, several interviewees, including Olivia and Laura, expressed scepticism about Blockchain's readiness. Adoption would likely require demonstration projects or international benchmarks to gain buy-in from the HSE and regulators. Olivia noted that without clear examples of successful implementation, Irish public institutions are unlikely to act due to their inherently risk-averse nature. Laura added that unless a tangible cost-saving or operational benefit is shown through trials, the HSE and HPRA would not proactively lead such transformation. Sarah mentioned that in a highly conservative and heavily regulated environment, companies fear becoming early adopters without knowing regulatory reactions.

Jane supported the need for pilots by referencing Dalsey, Hillblom and Lynn (DHL) digital innovation in logistics as a model for how successful transformation often begins with limited scope implementations. Emily also concurred and added the importance to the regulators of seeing a proof-of-concept or pilot first for assessment. All participants widely agreed that a controlled, government- or academia-backed pilot—featuring tight data controls, incentives, and stakeholder buy-in—would be the most effective strategy for proving the value of Blockchain. A proof-of-concept or pilot would also be typical of the industry as most life science organisations would trial new technologies, processes or initiatives at a reduced scale before expanding globally.

4.2.4 Governance Models and Incentives

Theme 4.1: Preference for Public-Private Partnerships

A clear consensus emerged in favour of neutral, multi-stakeholder governance structures. Interviewees endorsed models similar to the Irish Medicines Verification Organisation (IMVO) where the public sector regulates but implementation is led or co-funded by industry. Chloe recommended a model where public-private collaboration mirrors the IMVO's serialisation approach, ensuring oversight while allowing private sector innovation. Sarah proposed government-backed grants to reduce financial risk for companies entering

Blockchain pilots, adding that most life science companies would be familiar with the grant support process. He cited examples of Industrial Development Authority (IDA) funded Research, Development & Innovation (RD&I), training, digital transformation and green grants that are provided by EU funding via Irish state agencies.

Emily advocated for a neutral third-party system owner to avoid conflict of interest. Olivia stressed the need for public sector governance to ensure transparency and fairness, especially in how data is accessed and used. Laura highlighted that without a strong business case, the public sector is unlikely to drive Blockchain adoption alone, making private sector initiative and academic collaboration vital in early stages.

Theme 4.2: Financial and Regulatory Incentives

Financial incentives (e.g., funding, tax breaks), procurement preferences, and fast-track regulatory approvals were widely seen as essential to encourage industry participation. Olivia suggested weighting Health Technology Assessments (HTA) for companies offering real-time visibility, which could lead to quicker market approvals from the regulators. This view was supported by Laura who also noted that incentives such as expedited reimbursement decisions could boost adoption. Sarah added that companies would be more open to participating if they received government backed grant supports. Chloe, Jane and Emily pointed to regulatory benefits, such as simplified audit processes or preferential procurement consideration.

Chloe noted that a toll-bridge funding model could be effective, where costs are shared across beneficiaries until the infrastructure is paid off. Jane and Chloe supported regulatory incentives, for instance accelerated market approvals, and highlighted that smaller firms may benefit from a standardised integration process backed by regulatory support. Emily added that healthcare organisations would see huge benefits in traceability, visibility and reliability in a data-sharing solution. In his view procurement practices should favour organisations providing this data as they will gain the reassurance needed that they ‘know what they are getting and it’s of good quality’. Laura reinforced this message by stating that ‘real time data brings so many additional advantages…first and most importantly, enhanced patient safety which is a healthcare professionals primary concern’.

Collectively, interviewees reinforced that a blend of financial, operational, and regulatory motivations would be necessary to drive meaningful Blockchain adoption across the sector.

4.2.5 Willingness to Share Data Across Sectors

Theme 5.1: Conditional Support for Data Sharing

There is moderate to strong support for cross-sector data sharing under certain conditions: data standardisation, access control, and clear mutual value. Chloe and Jane stressed that alignment with existing compliance frameworks (e.g., Good Manufacturing Practice (GmP), HPRA protocols, procurement policies) would help ease transition. Each emphasised that any data-sharing system would need a clearly defined access model to prevent competitors from viewing commercially sensitive information.

Laura and Sarah highlighted that life sciences organisations would only participate if the system offered guarantees around data confidentiality and encryption. Olivia, echoed the majority views in that healthcare procurement processes should favour compliant suppliers who offer transparent data access, which could serve as a meaningful incentive while significantly improving the issue of drug shortages in Ireland. Several interviewees also noted that companies would require strict governance assurances around data usage, retention, and ownership.

Laura outlined how there would need to be a clear business case for the value of the Blockchain solution for the healthcare procurement teams and regulators to agree to the sharing of data.

Theme 5.2: Education and Awareness Gaps

Olivia and Sarah noted that misunderstandings and negative associations (e.g., Blockchain as "just crypto") could hinder adoption. Demonstrating concrete supply chain value through education and communication campaigns is critical. Sarah pointed out that a lack of understanding about Blockchain’s tangible benefits remains a barrier for senior decision-makers in both sectors. Laura shared that even though many recognise the inefficiencies in current supply chains, they may not yet associate Blockchain with a viable solution.

Jane and Chloe highlighted that early adopters could benefit from pilot programs supported by government or academic institutions to demonstrate value in practice. Emily was widely accepting of Blockchain as a future solution to resolve key pain points, as were Chloe and Jane, and expressed that inefficiencies resulting in high energy usage, storage and computing needs would need to be reduced or they could act as a barrier. Collectively, a shared emphasis was placed on communicating Blockchain’s regulatory, operational, and

ethical value propositions through industry workshops and government-backed digital transformation initiatives.

Conclusion of qualitative analysis

Research Objective	Key Insights
Identify current challenges with supply chain data access	Market size, lack of real-time data, interoperability, and siloed systems are critical issues
Evaluate benefits of Blockchain	Offers improved traceability, integrity, and auditability—but adoption depends on ROI and validation reforms
Assess technical challenges	Lack of standard data models, expensive infrastructure, and cybersecurity fears dominate
Understand demand for data-sharing	High interest across sectors, if confidentiality, governance, and incentives are clear
Determine feasibility	Feasible with regulatory and structural alignment. A consortium or pilot approach is necessary

Table 3: Key insights per research objective

The qualitative data collected aligns with and supports the mixed-methods approach defined in the research methodology. The thematic insights validate the research framework and illustrate that while Blockchain holds considerable potential to resolve systemic inefficiencies in Ireland's drug supply chain, operationalisation depends heavily on stakeholder trust, governance clarity, pilot implementations, and incentive alignment. Participants, in particular Chloe and Emily, who had broader awareness of data integration landscapes in life science organisations, were generally more attuned to the benefits of Blockchain and less risk adverse. This is indicative of disparity or gaps of awareness related to Blockchain between industry and professional backgrounds, suggesting the need to differ in approaches to raising awareness and knowledge within individual industries.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

This research explored the potential for blockchain technology to alleviate drug shortages in Ireland's public healthcare system by enabling cross-industry data-sharing between pharmaceutical manufacturers and healthcare providers. Drawing on a combination of extensive literature review, quantitative survey results, and qualitative interviews with subject matter experts, several key conclusions emerged.

5.1.1 The current challenges with supply chain data access for high demand drugs in Ireland's healthcare system

Drug shortages are a persistent and multifaceted issue within the Irish healthcare system. Root causes include global supply chain fragilities, manufacturing issues and delays, small market size and prioritisation challenges, regulatory delays, fragmented procurement systems, and lack of real-time data visibility. These factors combine to create inefficiencies that directly affect patient care, leading to delayed treatments and operational difficulties for healthcare providers.

Primary research confirmed that experienced healthcare and life sciences professionals perceive drug shortages as a frequent and highly disruptive issue. Survey responses indicated strong awareness and concern, with participants agreeing that improved supply chain transparency could significantly mitigate the severity and frequency of shortages.

5.1.2 The benefits of Blockchain in sharing of data related to critical drugs across manufacturing and healthcare organisations

Blockchain technology offers significant theoretical advantages in improving supply chain transparency, data integrity, and traceability. The immutable, decentralised nature of blockchain could provide healthcare providers with real-time, trusted information about the availability and movement of critical drugs, improving procurement decision-making and inventory management.

Survey respondents and interviewees both endorsed the potential benefits of blockchain, particularly its ability to streamline information flows, strengthen audit processes, and

support timely, data-driven procurement strategies. However, practical familiarity with blockchain implementations was relatively low among respondents, signalling a gap between perceived theoretical value and readiness for adoption. Proven case studies of Blockchain implementation in the highly regulated Healthcare and Life Science industries is pivotal to gaining general trust of the technology and its benefits.

5.1.3 The technical challenges of integrating data with Blockchain

Despite strong conceptual support, several barriers to blockchain adoption were identified, along with potential solutions. For instance, integrating blockchain solutions with legacy IT systems in healthcare and pharmaceutical sectors is a major technical and operational challenge. Developing standardised data models and engaging early with technology vendors to design interoperable systems that align with existing infrastructure is key. In addition, a cross-industry, cross-geography solution would benefit from standard terminology and taxonomy definitions to ensure maximum efficiencies.

Budget constraints, economic uncertainty, and willingness to co-fund projects in a proportionate manner could limit investment in new blockchain infrastructure. The provision and securing of grant funding from national and EU digital transformation initiatives and introduction of proof-of-concept pilots to demonstrate tangible value before scaling, could incentivise organisations to participate.

Concerns about protecting proprietary manufacturing and inventory data were highlighted during both the quantitative survey and qualitative interviews as a challenge preventing wider adoption. Implementing permissioned blockchain models combined with advanced encryption and zero-knowledge proofs to protect sensitive data while enabling necessary transparency is a must, particularly for private commercial manufacturing companies.

Misconceptions about blockchain's applications and risks were evident, with many participants involved in the primary research associating Blockchain with financial services such as crypto and Bitcoin, with references to Silk Road where Blockchain solutions were used illegally and unethically. Launching targeted education and communication programs through formal education providers, companies servicing the industry, working groups and industry collaboration partners to distinguish blockchain for healthcare and life science applications from cryptocurrency associations.

The need for compliance with GDPR and pharmaceutical regulations is a non-negotiable factor in the successful implementation of Blockchain. The use of Off-Chain Blockchain solutions, as highlighted in the secondary research Literature Review, is viable solution that addresses GDPR regulations. The positioning of Blockchain either as part of the manufacturing processes or downstream of same, would determine the level of regulatory approval required. Using Blockchain in parallel to the process would provide the necessary data to make the solution valuable, while acting as a tool or aide to support costly and complex audit processes, while not directly impacting the quality of the product. Blockchain's integration directly into GmP-compliant manufacturing processes would require significant changes to existing validation models to accommodate decentralised technologies, however it would potentially save the industry billions in operational efficiencies.

5.1.3.1 Upstream and Downstream Challenges

The central hypothesis of this research focused on the topic of manufacturing issues and delays as a potential cause of drug shortages, with secondary and primary research supporting this conclusion. However, further insights gleaned from qualitative interviews with key subject matter experts highlighted underlying issues both upstream and downstream of manufacturing processes. The primary research element of this research highlighted the following significant upstream and downstream challenges impacting the drug supply chain:

A. **Upstream Challenges:**
    - Difficulties in sourcing quality raw materials that are inputs to manufacturing, often resulting in higher volumes of defective drug products during the manufacturing process due to quality of raw materials.
    - Dependency on international suppliers, particularly from countries such as India and China, resulting in delays to key ingredients/materials required to meet manufacturing demand. This can result in knock-on effects in meeting market demand, where the issue is often attributed to the manufacturer rather than upstream supplier.

- Risks associated with counterfeit raw materials entering the supply chain, which are often difficult to pinpoint the origin of but associated with the manufacturer when issues arise.

B. **Downstream Challenges:**

- Ireland's slow market approval and drug reimbursement processes, managed by the HPRA as the regulator, often act as a barrier to prioritising Ireland as a market for the provision of timely and efficient access to novel drug treatments.
- Limited cold storage facilities, which require significant infrastructure investment, affect the storage and distribution of sensitive drugs, leading to manufacturers having to source drugs from other countries to meet increases in demand, despite being produced in Ireland.
- Small market size leading to stockpiling, parallel trading, and market de-prioritisation by pharmaceutical companies, leading to other countries with larger markets and higher priced private healthcare funding being prioritised for drug delivery.

These findings suggest that while manufacturing operations themselves are frequently and publicly highlighted as the cause of delays; they are often representations of symptoms rather than the underlying cause of delays. The research enforced the concept of Blockchain solutions being a viable solution, as a means to resolve not just the core manufacturing issues, but the upstream and downstream processes as well. Expanding the parameters of 'supply chain' to include sourcing of raw materials and the production of ancillary products would overall increase the quality of inputs to manufacturing. Through the use of smart contracts, and high data-transparency, incentives could be leveraged to address downstream issues such as reimbursements, quicker market approvals, stockpiling / parallel trading issues.

5.1.4 The demand for sharing of manufacturing, supply chain and drug administration data

This research has identified several key benefits of blockchain technology for addressing drug shortages and improving pharmaceutical supply chain performance in Ireland's public healthcare system.

Blockchain provides real-time visibility across the drug supply chain, allowing stakeholders to access a shared, tamper-proof record of production, storage, and distribution. This transparency enables quicker responses to shortages and supports more informed procurement decisions. The immutable nature of blockchain ensures that every action from batch release, quality checks to transport, is recorded permanently. This strengthens regulatory compliance, facilitates efficient audits, and ensures the integrity of pharmaceutical records.

Blockchain could also help prevent counterfeit or substandard raw materials from entering the supply chain by verifying the production and logistics lifecycle before acceptance by the manufacturer. When combined with technologies such as RFID and IoT, it offers robust protection for high-value or sensitive drugs. It should be noted that the ongoing Falsified Medicines Directive (FMD), serialisation programme by the EMA based on RFID technology, is in the process of being rolled out to prevent counterfeit whole products that have been distributed to the market. Incorporating upstream supply of materials using Blockchain would prevent many underlying issues which have knock-on and unseen effects on manufacturing.

Access to up-to-date supply data supports more strategic and timely procurement. Survey responses highlighted a willingness among healthcare professionals to prioritise suppliers that offer blockchain-based transparency, even if at slightly higher costs. Smart contracts and automated validation can also reduce administrative workloads and delays. Over time, these efficiencies may offset the high initial costs, improving both supply reliability and financial sustainability.

Blockchain can automate documentation for regulatory reporting and audit readiness. Features such as zero-knowledge proofs and off-chain storage offer GDPR compliance without sacrificing transparency or data security. It enhances trust by ensuring data integrity and enabling permission-based access. This addresses one of the major barriers to cross-sector collaboration: the fear of exposing commercially sensitive information.

Blockchain enables shared digital infrastructure that can underpin public-private partnerships. Models similar to the IMVO show how collaboration between industry and regulators can be scaled through technology to align goals and drive innovation.

5.2 Recommendations

Based on the conclusions above, the following recommendations are proposed to advance the operationalisation of blockchain in the Irish healthcare system.

5.2.1 Launch a Pilot Blockchain Programme for Acute Drug Shortage Products

Develop a government-backed pilot targeting high-risk drug categories (e.g., oncology, ADHD, and weight loss treatments), involving key stakeholders such as the HSE, HPRA, and pharmaceutical manufacturers. The pilot should address critical supply chain challenges and test permissioned, computationally efficient blockchain frameworks, including layer-2 or streamlined consensus algorithms. Key Performance Indicators (KPI) such as real-time visibility, response speed, and reduction in shortages should be benchmarked to evaluate blockchain's feasibility and value in improving data access and procurement decisions.

5.2.2 Establish Governance Structures and Secure Co-Funding for Blockchain Deployment

To ensure both adoption and sustainability, a national, multi-stakeholder public-private governance model, similar to the IMVO, should be established. The aim of the model should be to define data-sharing protocols, standardise terminology, and oversee ethical and regulatory compliance (e.g., GDPR, GmP). Concurrently, national and EU-level funding should be sought to support pilot initiatives, leveraging existing frameworks such as IDA digital transformation grants for example. Toll-bridge or co-funding models should also be explored to ensure affordability and encourage early-stage adoption across sectors.

5.2.3 Examine existing and desired Validation models for use of Blockchain in the life science manufacturing space

Further research should assess how blockchain can be integrated directly or indirectly within pharmaceutical manufacturing in a GmP-compliant manner. Off-chain and hybrid models show promise for GDPR compliance, but validation processes need to be explored further, particularly regarding their potential to streamline costly audits. An evaluation of in-line manufacturing implementation, where GmP compliance is critical, and downstream / parallel solutioning where Blockchain supports audit processes as a tool or an aide, should be conducted. Smart contracts should also be evaluated for automating quality control and procurement workflows. A regulatory sandbox could provide a safe environment for piloting

these use cases and generating feedback for industry and regulators.

5.2.4 Expand Use to Full Supply Chain Lifecycle and Align Procurement Incentives

Blockchain implementation should extend beyond manufacturing to include upstream suppliers and downstream healthcare systems. This would improve early risk visibility (e.g., raw materials), enable IoT-based environmental monitoring, and support procurement teams in prioritising transparent suppliers via smart contracts and HTA scoring. Linking blockchain adoption to faster reimbursements or regulatory approvals would incentivise broader industry participation and help address supply chain symptoms misattributed to manufacturing delays.

5.2.5 Promote Blockchain Awareness and Digital Upskilling

To overcome persistent knowledge gaps and public misconceptions, targeted education and awareness campaigns should be launched. These should involve academic institutions, industry associations, and state-backed agencies such as the IDA. Communication strategies should distinguish blockchain from cryptocurrency narratives and highlight its healthcare relevance. Sharing pilot outcomes and international case studies would build confidence and digital literacy, supporting cross-sector adoption.

5.2.6 Ensure Efficient and Sustainable Blockchain Solutions

To make blockchain commercially viable, concerns over energy consumption and algorithmic inefficiency must be addressed. Lightweight consensus mechanisms, semantic data models, and DAO-based governance should be trialled in proof-of-concept settings. Procurement frameworks should reward energy-efficient implementations, encouraging sustainable, scalable solutions that reduce operational costs while supporting healthcare and life sciences system resilience.

5.3 Limitations of the Research

This study offers valuable insights into the feasibility of using blockchain to reduce drug shortages through cross-industry data-sharing; however, several limitations should be considered when interpreting its findings.

The research was conducted within a limited academic timeframe, which constrained the

depth of analysis and the opportunity to explore long-term implementation scenarios or broader stakeholder engagement. Access to expert participants was also restricted. While the study drew on professionals from both healthcare and life sciences, the number with direct experience in blockchain implementation was relatively small, reflecting the niche nature of this emerging field.

In addition, blockchain remains a highly technical subject matter area, and many participants, particularly from the public healthcare sector, were unfamiliar with its applications beyond cryptocurrency. This limited the ability to gather deeply informed views on integration challenges, leading to some cautious or theoretical responses.

However, though 45 participants out of a range 120 completed the survey, saturation had been reached with this population, as patterns and themes began to recur during the analysis. This was reflective of the qualitative interviews where six out of 14 candidates took part in the interviews. After the initial four interviews, which incorporated an even spread across healthcare, life science and technology, saturation had been largely reached, with a lower number of additional insights gathered through the remaining two interviews.

External conditions further shaped the research context. Geopolitical and economic disruptions—such as Brexit, global supply chain instability, and post-COVID regulatory shifts—created an atypical operational climate. These evolving factors may have influenced the priorities and perspectives of participants, possibly limiting the generalisability of findings under more stable conditions.

Additionally, the absence of real-world blockchain implementations in Ireland's healthcare system meant the study relied on international case studies and theoretical frameworks. Without domestic pilots, empirical validation of feasibility and outcomes remained out of scope. The lack of clear regulatory guidance in areas such as GDPR and GmP compliance added further uncertainty around practical deployment.

In summary, while the research establishes a strong foundation, its findings should be viewed as exploratory. Broader studies involving more stakeholders, greater technical engagement, and real-world pilots will be essential to validate and build upon the conclusions presented here.

5.3.1 Future Work

To build on the insights gained through the secondary and primary research, further topics and themes would benefit from deeper analysis. This includes expanding a quantitative survey to a larger population for each of the disciplines, backgrounds and industry representatives to ensure clear correlations can be determined. The addition of more participants with either theoretical or practical experience of Blockchain would allow for further examination of its technical components.

Broadening the qualitative interview pool to include stakeholder groups identified in this research, such as public sector and regulators, would bring different viewpoints to the analysis. Representatives from the Life Science industry could be widened to include those with commercial or market access experience. This would advance the area of research into Public-Private Partnerships which emerged as the preferred model for governance and funding.

In-depth secondary research into the EU's FMD serialisation initiative which, though focused on counterfeit drug prevention, has many parallel requirements and challenges that could be leveraged. In particular, a review of the regulatory considerations, governance and how the industry is adopting the technology while maintaining compliance, could provide practical evidence of how this type of technology could be widely adapted.

An analysis of suitable Blockchain solutions and architectures would support with addressing challenges such as inefficiencies. In addition, it could serve to dispel negative perceptions of Blockchain and lack of awareness of Blockchain's benefits through evidence backed research.

Further studies into the wider supply chain would be beneficial, as the research highlighted the underlying causes of many manufacturing issues as originating further upstream in the supply chain, where Blockchain could add value in ensuring higher quality raw materials.

5.4 Closing Summary

Blockchain technology presents a transformative, albeit complex, opportunity to enhance the resilience, transparency, and responsiveness of Ireland's pharmaceutical supply chain. As this research has shown, the root causes of drug shortages extend far beyond

manufacturing inefficiencies, encompassing fragmented data systems, limited supply chain visibility, regulatory bottlenecks, and inconsistent procurement practices. Blockchain—when thoughtfully implemented—can address many of these challenges by enabling secure, real-time data-sharing between pharmaceutical manufacturers, healthcare providers, and regulatory authorities.

While barriers such as integration complexity, regulatory ambiguity, and industry trust must not be underestimated, they are not insurmountable. A pragmatic, phased, and partnership-driven approach—grounded in pilot projects, regulatory collaboration, and shared governance—will be critical in overcoming resistance and building momentum. Furthermore, aligning blockchain deployment with broader digital transformation goals in healthcare and life sciences can attract funding, drive innovation, and create new models for collaborative public-private engagement.

The potential outcomes are compelling: improved availability of critical medicines, stronger defences against counterfeits, reduced audit burdens, smarter procurement practices, and ultimately, better patient care. If supported by strong leadership, policy alignment, and targeted investment, blockchain could serve as a foundational tool for a more secure, equitable, and future-ready pharmaceutical supply ecosystem in Ireland and beyond.

6. REFERENCES AND BIBLIOGRAPHY

1. O'Regan, E. (2023) 'Asthma inhalers and epilepsy drugs among 247 medicines now out of stock in Irish pharmacies', Irish Independent, 20 February 2023. Available at: https://www.independent.ie/irish-news/health/asthma-inhalers-and-epilepsy-drugs-among-247-medicines-now-out-of-stock-in-irish-pharmacies/42349709.html#:~:text=%E2%80%8BMedicines%20in%20short%20supply,the%20Health%20Products%20Regulatory%20Authority.
2. Kirby, J. (2024). 'Warning over fake weight loss jabs as shortage of diabetic drug continues' The Telegraph, 05 August 2024. Available at: https://www.telegraph.co.uk/news/2024/08/05/do-not-buy-fake-weight-loss-jabs-online-warn-pharmacists/
3. Mulligan, J. (2024). 'Patients experience delay in chemotherapy treatment due to supply issues.' Irish Independent, 27 August 2024. Available at: https://www.independent.ie/regionals/louth/drogheda-news/when-it-comes-to-treatment-every-single-day-matters-states-louth-deputy-as-cancer-patients-in-experience-delays-to-chemotherapy-treatment-due-to-supply-issues/a704015850.html
4. Graham, B. (2023). 'Epilepsy drug shortage causing 'distress and worry'' Evening Echo, 24 March 2023. Available at: https://www.echolive.ie/corknews/arid-41101261.html
5. Horgan, S. (2023) 'Concerns over medication rationing in Cork', Evening Echo, 03 March 2023. Available at: https://www.echolive.ie/corknews/arid-41084527.html
6. O'Regan, E. (2022). 'Medicine shortage has lead to use of drugs not licenced in Ireland.' Irish Independent, 3 September 2022. Available at: https://www.independent.ie/irish-news/medicine-shortage-has-lead-to-use-of-drugs-not-licenced-in-ireland/41958217.html
7. Health Products Regulatory Authority (HPRA). (2023). Medicines Shortages Framework \u2013 A Multi-Stakeholder Approach. (SUR-G0045-Medicines-Shortages-Framework-v4.pdf)
8. Health Service Executive (HSE). (2024). Strategy for the Procurement of Medicines in Acute & Non-Acute Hospitals. (HSE-Strategy-for-the-Procurement-of-Medicines-in-Acute-Non-Acute-Hospitals.pdf)
9. Griffin, N. (2023). 'Ozempic Diabetes drug in short supply as its use for weight loss goes viral.' Irish Examiner, 16 June 2023. Available at: https://www.irishexaminer.com/news/arid-41163385.html
10. Bowers, F. (2025). 'What is causing delayed access to new cancer medicines?' RTE News, 10 May 2025. Available at: https://www.rte.ie/news/analysis-and-comment/2025/0510/1512043-health-cancer-medicine/
11. O'Regan, E. (2023). 'Ozempic shortage for diabetics due to production glitch comes as more people use the drug to lose weight'. Irish Independent, 2 September 2023. Available at: https://www.independent.ie/irish-news/ozempic-shortage-for-diabetics-due-to-production-glitch-comes-as-more-people-use-the-drug-to-lose-weight/a1330925772.html
12. O'Regan, E. (2024). 'Cancer and ADHD treatments hit by supply problems as medicines shortage continues'. Irish Independent, 07 September 2024. Available at: https://www.independent.ie/irish-news/health/cancer-and-adhd-treatments-hit-by-supply-problems-as-medicines-shortage-continues/a1548061963.html

13. Griffin, N. (2023) ‘Antibiotics, cough syrups and blood pressure tablets among 239 out-of-stock medications’. Irish Examiner, 08 February 2023. Available at: https://www.irishexaminer.com/news/arid-41066186.html
14. Andanda, P. and Mlotshwa, L. (2024) ‘Streamlining the Ethical-Legal Governance of Cross-Border Health Data Sharing during Global Health Emergencies’. Research Ethics, 20(4), pp. 812–834. DOI: 10.1177/17470161241261907.
15. DiVito, L., van Wijk, J. and Wakkee, I. (2021) ‘Governing Collaborative Value Creation in the Context of Grand Challenges: A Case Study of a Cross-Sectoral Collaboration in the Textile Industry’. Business & Society, 60(5), pp. 1092–1131. DOI: 10.1177/0007650320930657.
16. Goldsby, C. and Hanisch, M. (2022) ‘The Boon and Bane of Blockchain: Getting the Governance Right’. California Management Review, 64(3), pp. 141–168. DOI: 10.1177/00081256221080747.
17. Griffiths, J., et al., 2023. Data sharing in agricultural supply chains: Using semantics to enable sustainable food systems. Journal of Supply Chain Innovation, 17(3), pp. 45-59.
18. Hodapp, D., and Hanelt, A., 2022. Interoperability in digital innovation ecosystems: A blockchain perspective. Information Systems Review, 14(2), pp. 28-49.
19. Huser, V., Shmueli, G., and Blumberg, J., 2018. Data-sharing platforms for de-identified data from human clinical trials: Challenges and solutions. Health Informatics Journal, 12(4), pp. 91-107.
20. Islam, M., et al., 2022. Vulnerability prediction for secure healthcare supply chain service delivery: A blockchain-based approach. Journal of Blockchain Research, 15(1), pp. 18-33.
21. Kagoya, H., et al., 2020. A model to strengthen the utility of quality pharmaceutical health systems data in resource-limited settings. Global Health Review, 8(5), pp. 32-41.
22. Lavorgna, A., 2014. The online trade in counterfeit pharmaceuticals: New criminal opportunities, trends, and challenges. Crime and Society, 10(3), pp. 77-92.
23. Matulevičius, R., et al., 2022. Ontological representation of healthcare application security using blockchain technology. International Journal of Health Technology, 16(4), pp. 61-74.
24. Javed, L. et al. (2023) ‘ShareChain: Blockchain-enabled Model for Sharing Patient Data Using Federated Learning and Differential Privacy’. Expert Systems, 40(5), pp. 1–17. DOI: 10.1111/exsy.13131.
25. Cruz, C.O. and Marques, R.C. (2013) ‘Integrating Infrastructure and Clinical Management in PPPs for Health Care’. Journal of Management in Engineering, 29(4), pp. 471–481. DOI: 10.1061/(ASCE)ME.1943-5479.0000166.
26. Tafuro, Alessandra, Giuseppe Dammacco, and Antonio Costa. 2023. A Conceptual Study on the Role of Blockchain in Sustainable Development of Public–Private Partnership. Administrative Sciences 13: 175. https://doi.org/10.3390/admsci13080175
27. Gonçalves, R.M., da Silva, M.M. and da Cunha, P.R. (2024) ‘Olympus: A GDPR Compliant Blockchain System’. International Journal of Information Security, 23(2), pp. 1021–1036. DOI: 10.1007/s10207-023-00782-z.Schwabe, G., et al., 2019. The role of public agencies in blockchain consortia: Learning from the car dossier initiative. Public Sector Technology Journal, 11(2), pp. 24-39.
28. Rikken, O. et al. (2019) ‘Governance Challenges of Blockchain and Decentralized Autonomous Organizations’. Information Polity: The International Journal of

Government & Democracy in the Information Age, 24(4), pp. 397–417. DOI: 10.3233/IP-190154.
29. Srivenkateswaran, C., et al., 2024. Securing healthcare data: A federated learning framework with hybrid encryption in cluster-based blockchain networks. Journal of Secure Data Innovation, 21(6), pp. 15-30.
30. Sodhi, M., et al., 2022. Why emerging supply chain technologies initially disappoint: Blockchain, IoT, and AI. Supply Chain Dynamics Journal, 29(3), pp. 110-125.
31. Sun, L., 2024. Construction of supply chain management information systems based on networked web service composition: A blockchain-based approach. Journal of Emerging Technologies, 19(1), pp. 52-68.
32. Vargas, L., and Mira da Silva, M., 2023. Smart contracts in healthcare: Enabling efficiency and compliance through blockchain. Technology in Health Administration, 12(7), pp. 89-104.
33. Yen-Ting, L., et al., 2022. Identifying and overcoming barriers to implementing blockchain in supply chains. Supply Chain Management Review, 16(3), pp. 41-56.
34. Zhang, J., et al., 2022. Facing disruption: Learning from the healthcare supply chain responses in British Columbia during the COVID-19 pandemic. Global Logistics Journal, 14(2), pp. 20-33.
35. Zimmerman, C., 2006. Protecting the pharmaceutical supply channel: Best practices and blockchain integration. Pharmaceutical Logistics Quarterly, 4(1), pp. 12-22.
36. Zhu, Y., 2024. Research on evolutionary game theory of digital twin data information sharing based on blockchain technology. International Journal of Computational Economics, 25(2), pp. 91-112.
37. Dibley, L. (2011) ‘Analysing narrative data using McCormack’s Lenses.’, Nurse Researcher, 18(3).

7. Appendix

A. Quantitative Survey Questionnaire

#	Question
1	What industry best describes your academic / career background? (Select one)
2	What type of organisations do you work most closely with in your career? (On average over past three years).
3	What area of expertise describes your background most accurately?
4	How many years of experience do you have in working with your chosen sector?
5	Are you aware of drug shortages in the Irish healthcare system?
6	If yes, how frequently do you perceive there to be drug shortages?
7	In your opinion, which categories of drugs are most affected by shortages? (Select all that apply)
8	How would you describe the nature of drug shortages?
9	How significant is the impact of drug shortages on patient care, in your opinion? (Scale 1–5: 1 = No Impact, 5 = Severe Impact)
10	In your opinion, what are the primary causes of drug shortages in Ireland? (Please move and rank the options below where the top answer is most likely cause of shortages)
Please select the option that best describes your opinion related to the statements below.	
11	Greater transparency in pharmaceutical supply chains would help mitigate drug shortages.
11	Improved healthcare procurement processes and incentives are needed to mitigate drug shortages
11	Pharmaceutical manufacturers should be required to provide real-time supply chain data to healthcare providers
12	How familiar are you with Blockchain technology?
13	Blockchain technology allows for immutable, secure, and transparent data sharing. Do you agree organisations in your area of expertise would be open to using Blockchain for supply chain visibility...
14	What do you believe would be the greatest benefits of a Blockchain-enabled supply

	chain? (Select up to 3)
15	Rank the following concerns from most to least important in preventing Blockchain adoption (Top = most important, Bottom = least important):
16	Do you believe there would be benefits in a bi-directional data-sharing model where healthcare procurement data (e.g., forecasted demand) is securely shared with pharmaceutical manufacturers to optimise supply chain management?
Please select the option that best describes your familiarity with aspects of Blockchain below.	
17	How familiar are you with the technical implementation of Blockchain?
17	How familiar are you with Blockchain's regulatory and compliance landscape?
17	How familiar are you with real-world use cases of Blockchain?
Please select the option that best describes your familiarity with aspects of Blockchain below.	
18	How familiar are you with the technical implementations, regardless of technology?
18	How familiar are you with regulatory and compliance landscapes in Healthcare & Life Sciences?
18	How familiar are you with 3rd party data sharing arrangements across organisations?
19	If data is shared by private pharmaceutical companies and consumed by public health organisations: who, in your opinion, should be responsible for governing a Blockchain-enabled drug supply chain system?
20	How should such a Blockchain system be funded?
Please select the option that best describes your opinion related to the statements below:	
21	The availability of transparent, real-time supply chain data would influence healthcare procurement decisions toward pharmaceutical companies who can provide it.
21	Prioritising procurement from pharmaceutical companies that provide full transparency via Blockchain, should be done, even if at a slightly higher cost.
22	Are there any additional comments or concerns you would like to share about drug shortages, manufacturing operations, supply chain transparency, or Blockchain adoption?

B. Qualitative Interview Question Pack #1

Interview Questions

Background and Context

1. Can you describe your background and experience within healthcare or life sciences sector?
2. In your experience, have you encountered, or are aware of, instances of drug shortages in a healthcare setting?

Supply Chain Challenges

The HPRA have previously stated that 60% per cent of reported shortages are related to delays in manufacturing, while 53% of survey respondents identified ‘Supply chain disruptions’ as a major cause.

3. What do you perceive as the primary causes of drug supply delays? (Manufacturing, supply chain, regulatory factors?)
4. What are the main supply chain challenges in ensuring reliable access to critical medications in your opinion? (Procurement practices, real-time data, market size etc.)
5. To what extent would real-time data access improve availability?

Perspectives on Blockchain Technology

6. Have you heard of Blockchain technology before? If so, what is your general understanding of it?
7. What potential benefits could a real-time, transparent data system offer in drug supply?
8. Survey results highlighted that 44% expressed concerns about 'Regulatory and compliance challenges'. Would this be of concern to you and are there any other challenges you foresee with Blockchain for data-sharing?

Governance & Funding

9. Who should be responsible for managing a Blockchain-enabled system? Public sector, Private sector, Academia or Pubic Private Partnerships?

10. What roles should stakeholders (government, private companies, regulators) have to ensure transparency, compliance, data quality and reliability?
11. How should such a system be funded?

Trust & Adoption

13. What factors influence your trust in a Blockchain-based data-sharing system?
14. In your opinion, would the HSE consider adopting a new system if it improves drug availability and transparency? Why or why not?
15. What security concerns do you believe life science organisations would have about sharing real-time manufacturing and supply chain data?
16. How likely is industry-wide adoption of Blockchain systems?

Value in data sharing

17. In your opinion, should healthcare procurement processes favour suppliers who can provide real-time access to manufacturing and supply chain data?
18. If such a data-sharing mechanism was in place, what incentives, if any, should be provided to life science organisations.

Conclusion

19. Is there anything else you would like to share around the integration of life science and healthcare industries through Blockchain, to reduce drug shortages?

C. Qualitative Interview Question Pack #2

Section 1: Background and Context

1. Can you describe your current role and experience across the areas of life sciences manufacturing, digital technologies, or data management?
2. What exposure have you had to initiatives integrating digital technologies like Blockchain in pharmaceutical manufacturing or distribution?
3. In your experience, what are the key pain points in end-to-end visibility across pharmaceutical supply chains?

Section 2: Supply Chain & Data Sharing Challenges

4. From your perspective, what are the primary root causes of drug shortages in pharma manufacturing? (e.g., demand planning, production delays, raw material availability, supply chain bottlenecks)
5. What challenges do you see in achieving data interoperability across life sciences manufacturers, distributors, and downstream stakeholders (e.g., pharmacies, hospitals)?
6. How significant is the lack of real-time or near-real-time data in your view? Would improved visibility influence operational or strategic outcomes?

Section 3: Blockchain Technology Perspectives

7. What is your understanding or practical experience of Blockchain solutions in manufacturing or other areas?
8. Do you see Blockchain as a viable solution for addressing data fragmentation in the pharma supply chain? Why or why not?
9. What technical or operational challenges do you anticipate in deploying Blockchain solutions at scale across the pharmaceutical ecosystem?

Section 4: Standards, Compliance & Governance

10. In the context of GmP, how compatible is Blockchain-based traceability with current compliance obligations?

11. What challenges do you foresee in aligning Blockchain implementations with global regulatory frameworks (e.g., FDA, EMA, ISO standards)?
12. Who should ideally own or govern a Blockchain-based supply chain data infrastructure—manufacturers, consortia, regulators, healthcare or a neutral third party?

Section 5: Security, Trust & Adoption

13. What are the key security concerns associated with sharing manufacturing and supply chain data on a distributed ledger?
14. From a data integrity and trust perspective, how does Blockchain compare with more traditional secure data exchange platforms (e.g., APIs, EDI)?
15. What factors would most influence industry-wide adoption of Blockchain platforms in pharma manufacturing (e.g., ROI, regulatory clarity, technology maturity)?

Section 6: Value Creation & Incentives

16. What potential commercial or operational benefits could manufacturers derive from participating in a transparent, Blockchain-enabled data-sharing network?
17. Would you support procurement preference for manufacturers who offer real-time data visibility as part of their value proposition? Why or why not?
18. What types of incentives—financial, regulatory, reputational—could help drive wider adoption across the pharma ecosystem?

Section 7: Looking Ahead

19. Are there any pilots, proofs-of-concept, or Blockchain consortia (e.g., MediLedger, PharmaLedger) you're familiar with or involved in?
20. In your opinion, what does an ideal future state for integrated data-sharing across life sciences manufacturing look like?
21. Is there anything else you'd like to share about the role of Blockchain in enabling next-generation pharma supply chain transformation?

D. Individual Participant Responses

Participant: Olivia Jones

Date: 31 March 2025, 15:30 pm

Interview Notes:

Section 1: Background & Experience

1. Donal Cronin: Let's begin with your background. Could you describe your experience within healthcare or life sciences?

Olivia Jones: Sure. I've worked as a pharmacist for around ten years before transitioning into a director role in healthcare and life sciences consulting. Lately, my focus has been more on corporate healthcare. I've worked across various healthcare settings, including community pharmacy and corporate consultancy. It's given me insights into the challenges of managing supply chains and ensuring consistent availability of essential medications.

2. Donal Cronin: Based on your experience, have you encountered or are you aware of drug shortages in healthcare settings?

Olivia Jones: Yes, absolutely. Drug shortages have been much more noticeable compared to pre-COVID times, especially for infection-related and over-the-counter medications. It's becoming increasingly difficult to find suitable substitutes when certain medications aren't available. The situation is particularly challenging for patients with chronic conditions who rely on specific medications.

Used to be able to substitute drugs for others if short a lot easier, it has gotten more difficult in the past 5 years. Over the counter drugs such as antibiotics for example are in shortage. General Practitioners (GP) are also prescribing different drugs now as they know there are shortages.

Section 3: Supply Chain Challenges

3. Donal Cronin: What do you think are the primary causes of these shortages? Are they related to manufacturing, supply chain, or regulatory issues?

Olivia Jones: I believe the delays are mostly related to supply chain issues rather than manufacturing problems. Regulatory approval processes are slow, and Ireland's small market size doesn't help. It's difficult for suppliers to prioritise our market. The issue is further compounded by a lack of coordination between different stakeholders. Smaller markets like Ireland often get deprioritised when there are global shortages.

4. Donal Cronin: What are the main supply chain challenges in ensuring reliable access to critical medications in your opinion?

Olivia Jones: The path to market approval for drugs is very slow. Numerous IPHA events call this out consistently. The market approval process is not fit for purpose. The size of the market is too small to be commercially prioritised.

5. Donal Cronin: To what extent would real-time data access improve availability?

Olivia Jones: From the healthcare and market perspective, we're too far behind in Ireland for real-time data to be a solution. We still don't have patient health records are there are other fundamental issues to be resolved such as market approvals and our market size. There could be benefits from the supply chain side.

Section 4: Perspectives on Blockchain Technology

6. Donal Cronin: Have you heard of Blockchain technology before? If so, what is your general understanding of it?

Olivia Jones: My understanding of blockchain is quite limited. I mostly associate it with finance, but I know there are potential applications in healthcare. I'm not entirely sure about the benefits or challenges, though. I can see how it could be useful for improving transparency and traceability, but I'd need to learn more about how it could be practically applied within healthcare supply chains.

Have been on a few talks on it but mostly associate it with Finance and Bitcoin.

7. Donal Cronin: What potential benefits could a real-time, transparent data system offer in drug supply?

Olivia Jones: not really knowledgeable in the area and more fundamental issues.

Real-time data could be useful, but it's not a solution to everything. There are broader structural issues in the Irish market that wouldn't be resolved simply by improving data

availability. While real-time data sharing could help identify problems earlier, there needs to be a broader strategy in place to address supply chain inefficiencies.

8. Donal Cronin: Survey results highlighted that 44% expressed concerns about 'Regulatory and compliance challenges'. Would this be of concern to you and are there any other challenges you foresee with Blockchain for data-sharing?

Olivia Jones: no real concern, each organisation would have to be compliant anyway or would not be feasible.

Section 5: Governance & Funding

9. Donal Cronin: Who should be responsible for managing a Blockchain-enabled system? Public sector, Private sector, Academia or Pubic Private Partnerships?

Olivia Jones: I'd favour a public-private partnership. The data shared through such systems shouldn't be commercially sensitive and should be accessible to all relevant stakeholders. It's about creating a collaborative environment where everyone can benefit. However, without clear governance structures, it's going to be difficult to get everyone on board.

10. Donal Cronin: What roles should stakeholders (government, private companies, regulators) have to ensure transparency, compliance, data quality and reliability?

Olivia Jones: Government / Public sector should regulate. The HPRA already regulates data given to it by the life science industry already and would be best placed.

11. Donal Cronin: How should such a system be funded?

Olivia Jones: Private only companies should fund the solution given their strong profit margins, with tight governance from public sector.

Section 6: Trust & Adoption

12. Donal Cronin: Do you foresee any challenges related to trust and adoption of blockchain technology in healthcare?

Olivia Jones: No issues with the data being available. It would be dependent on what the data is but shouldn't be an issue. Maybe the life science companies would.

13. Donal Cronin: In your opinion, would the HSE consider adopting a new system if it improves drug availability and transparency? Why or why not?

Olivia Jones: I doubt it. Looking at how slow the market approval process is, despite the urgency and it being talked about for a long time. They seem to like making it hard for themselves. The solution would have to be funded by the private sector.

14. Donal Cronin: What security concerns do you believe life science organisations would have about sharing real-time manufacturing and supply chain data?

Olivia Jones: It's commercially sensitive data to them so it would have to be guaranteed to be secure and private.

15. Donal Cronin: How likely is industry-wide adoption of Blockchain systems?

Olivia Jones: The understanding isn't there yet. Even if the data isn't commercially sensitive, clear communication and education are necessary to build trust among stakeholders. People need to understand how the system works and what benefits it offers. Without that understanding, there will always be resistance. The HSE are also slow to move and face legacy issues. There is a negative perception to Blockchain publicly. I would not trust my own personal patient records with Blockchain.

Section 7: Value in Data Sharing

16. Should healthcare procurement processes favour suppliers who can provide the data?

Olivia Jones: Yes absolutely. They should incentivise anyway they can as it is a mess at the moment. This would be the best alternative and should be incentivised to reduce issues.

17. Donal Cronin: If such a data-sharing mechanism was in place, what incentives, if any, should be provided to life science organisations.

Olivia Jones: Life science organisations should be incentivised through better weighting in HTAs for providing access to real-time data. This will speed up market approvals which is very attractive to life science companies.

Financial incentives are always a good starting point, but there's also a need for practical benefits. If companies can see that participating in a blockchain system will improve their efficiency or help them avoid penalties for non-compliance, they're more likely to get involved.

Section 8: Incentives & Challenges

18. Donal Cronin: Is there anything else you would like to share around the integration of life science and healthcare industries through Blockchain, to reduce drug shortages?

Olivia Jones: Apart from technical challenges, there's also the issue of buy-in from stakeholders. Some companies are simply not interested in changing their existing processes, especially if they don't see a clear benefit. Education and awareness-raising will be key to overcoming that resistance.

There should be a customer / patient portal in pharmacies to enable them to make more informed decisions on which drugs to dispense.

The market size in Ireland is too small with five million people. The life science companies would want to expand EU wide at least to make commercially feasible.

Participant: Sarah Smith

Date: 4 April 2025, 16:00 pm

Interview Notes:

Section 1: Background & Experience

1. Donal Cronin: To start, could you describe your background and experience in the healthcare or life sciences sectors?

Sarah Smith: Sure. I've been working as a consultant for about 13 years, with most of that time spent in healthcare and life sciences. I've been involved in project management, process improvement, and large-scale transformation programs, including work for @@Large international life science company## and various global healthcare consultancies.

My experience spans both Ireland and Australia, focusing on healthcare transformation, managing multi-disciplinary teams, and working on policy implementation. I've dealt with everything from strategic planning to practical execution of large-scale projects.

2. Donal Cronin: From your experience, are you aware of any drug shortages within healthcare settings?

Sarah Smith: Not directly, but I'm aware of it from a general standpoint. Supply chain disruptions, global demand increases, and pricing disparities all contribute to shortages. I've heard of issues with basic medications, including ADHD and blood pressure medications which the HPRA maintain lists of shortages. There seems to be a lack of coordination and communication across the supply chain, which exacerbates the problem.

I also know that during the pandemic, there were significant disruptions in manufacturing and logistics, which caused availability issues for certain drugs. Ireland's smaller market size makes it especially vulnerable to these kinds of disruptions.

Section 3: Supply Chain Challenges

3. Donal Cronin: What do you think are the primary causes of these shortages? Manufacturing, supply chain, regulatory factors, or others?

Sarah Smith: I'd say a combination of factors. Manufacturing issues are significant, but procurement practices, regulatory hurdles, geopolitical instability, and tariffs all play a part. Market size is another consideration—smaller markets like Ireland may not be prioritised.

Some countries being able to pay more is certainly an issue. Where you have Public vs Private systems, for example, the US could pay higher value for drugs than Ireland. Global population increases are putting pressure on demand, particularly if inventory is limited. COVID issues are still persisting.

4. What are the main supply chain challenges in ensuring reliable access to critical medications in your opinion? (Procurement practices, real-time data, market size etc.)

Sarah Smith: For profit prioritisation of distribution is a big issue. Regulations can impact on supply and cause delays. Ireland's small market size is a big issue. Geopolitical issues, such as tariffs, are having an impact.

5. To what extent would real-time data access improve availability?

Sarah Smith: Yes, 100%, absolutely. Not sure of what the incentives might be for the life science manufacturers, however.

Donal Cronin: Do you think real-time data sharing could help address some of these issues?

Sarah Smith: It could, but it depends on the incentives. Faster reimbursement or regulatory approval could be powerful motivators for companies to share data more openly.

Real-time data sharing could also help identify shortages before they become critical, but it requires cooperation across the entire supply chain. Without buy-in from key stakeholders, it won't be effective.

Section 4: Perspectives on Blockchain Technology

6. Donal Cronin: What's your understanding of Blockchain technology, and do you see potential benefits in applying it to healthcare?

Sarah Smith: I have a general awareness of blockchain, but I'm not an expert. It seems promising in terms of transparency and traceability, but I'm sceptical about its adoption, especially from a profit-driven perspective. The incentives for private companies aren't always clear.

From what I understand, blockchain could enhance data security and streamline the sharing of information across the supply chain. But unless companies see a clear financial or strategic benefit, adoption will be slow.

7. What potential benefits could a real-time, transparent data system offer in drug supply?

Sarah Smith: Loads of benefits for the HPRA, maybe not as much for the life science manufacturers. Would help with being able to predict and forecast better. Great for inventory management. Could help streamline regulatory processes. Mitigate risk of counterfeits entering the market.

8. Survey results highlighted that 44% expressed concerns about 'Regulatory and compliance challenges'. Would this be of concern to you and are there any other challenges you foresee with Blockchain for data-sharing?

Sarah Smith: Currently not the norm so trust would be a factor. Would be hesitant to adopt, particularly in a risk-adverse industry, in the event that sharing commercially sensitive data could be accessed incorrectly, essentially airing your dirty laundry.

If you are found to be non compliant, because of it's immutability, it will be on record forever and this may not be attractive for companies.

Section 5: Governance & Funding

9. Donal Cronin: Who should manage a blockchain-based system? The public sector, private sector, academia, or a combination?

Sarah Smith: I'd suggest a government-backed approach, ideally with grants or funding incentives to encourage companies to participate. There needs to be alignment between private and public interests. The government can provide the regulatory framework, but the private sector needs to be involved in implementation.

Public-private partnerships could be effective, but it's essential to ensure that all stakeholders are represented and that the governance structure is robust enough to handle potential conflicts of interest.

10. Donal Cronin: What roles should stakeholders (government, private companies, regulators) have to ensure transparency, compliance, data quality and reliability?

Sarah Smith: The HPRA would be the ideal regulator in a public-private partnership arrangement.

11. Donal Cronin: How should such a system be funded?

Sarah Smith: Private life science companies sharing the costs with grants provided by the government. Organisations will be used to grant funding processes already. Examples of this would be the RD&I and Digitalisation grant supports currently. It would also support adjacent industries who service the life science industry.

Section 6: Trust & Adoption

12. Donal Cronin: What about challenges related to trust and adoption of blockchain technology?

Sarah Smith: Funding and incentives could help overcome some of the reluctance. However, there's still a lack of understanding about how blockchain would provide tangible benefits to the industry.

There's also the issue of trust—companies are often reluctant to share sensitive information unless they're confident it won't be misused. Demonstrating the practical benefits of

blockchain is crucial if you want widespread adoption.

It would need mass adoption or specific use cases. Being the first company to do anything is always going to be risky.

20. Donal Cronin: In your opinion, would the HSE consider adopting a new system if it improves drug availability and transparency? Why or why not?

Sarah Smith: Definitely, yes. The new @@leader in a key and relevant role## would absolutely go for something like this.

21. Donal Cronin: What security concerns do you believe life science organisations would have about sharing real-time manufacturing and supply chain data?

    Sarah Smith: since most companies are private for-profit organisations, if commercially sensitive data became public it would cause serious issues. For example, if people know that a company is oversupplied in a particular drug, procurement practices could lower their prices based on supply and demand. So there is a financial angle to consider. If real-time prod data is leaked, costs per unit could be known.

    If bad actors discover a site has a large amount of valuable product in it's inventory, it could be targeted.

22. Donal Cronin: How likely is industry-wide adoption of Blockchain systems?

N/A - answered through other questions.

Section 7: Value in Data Sharing

23. Donal Cronin: In your opinion, should healthcare procurement processes favour suppliers who can provide real-time access to manufacturing and supply chain data?

Sarah Smith: Its certainly a factor, but some companies may not be able to and aren't having any challenges currently either. If it did favour those who do provide data, then it would encourage others to sign up.

24. Donal Cronin: If such a data-sharing mechanism was in place, what incentives, if any, should be provided to life science organisations.

Sarah Smith: Financial incentives are the most obvious, but regulatory incentives might be

more effective. For example, providing companies with faster approval processes or preferential treatment for adopting blockchain-based systems could be appealing.

Not sure, there would have to be some. Favouring suppliers in procurement and government grant support would be incentives.

25. Donal Cronin: Is there anything else you would like to share around the integration of life science and healthcare industries through Blockchain, to reduce drug shortages?

Sarah Smith: Cultural resistance and a lack of understanding about the technology are major barriers. Without education and training, people are likely to dismiss it as a fad or something that's too complicated to implement effectively.

Public-Private Partnerships would be the best model, but privates should want to be more engaged. It would benefit them to have stronger relationships in the public sector.

Participant: Chloe Wilson

Date: 1 April 2025, 09:00am

Interview Notes:

Background and Experience

1 Donal Cronin: Can you describe your background and experience in various sectors to date?

Chloe Wilson: I'm a scientist by training, with a PhD focused on developing novel antimalarial drugs. I worked at @@a clinical trials company##, and then at @@leading life science industry-wide and government agency partner##, supporting the industry in manufacturing capabilities, quality, regulatory affairs, supply chain, and external manufacturing. I have over 10 years of experience, particularly in medicine shortages and Brexit's impact on the Irish market.

My work has involved developing novel antimalarial drugs, supporting manufacturing capabilities, and acting as a bridge between industry and regulators like the HPRA. I was involved in establishing @@leading life science industry-wide organisation##, as a

division of government investment agency##, where I was working closely with manufacturers and stakeholders to improve manufacturing capabilities in Ireland. I was also part of the efforts to address shortages in certain essential medicines.

2 Donal Cronin: In your experience, have you encountered or have an awareness of instances of drug shortages in healthcare settings?

Chloe Wilson: Yes, particularly while working at @@leading life science industry-wide organisation##. Challenges often arise from poor communication of data and disruptions in the supply chain. For example, during COVID-19, there were shortages of basic medications, particularly over-the-counter drugs. The lack of visibility across the supply chain made it difficult to accurately predict and manage shortages. The HPRA often received late notifications of shortages, despite European regulations requiring advance notice. The average notice was far shorter than required, leading to efforts to understand and mitigate these shortages.

The average notice time was 12 days which was far shorter than the required 30 days. The HPRA couldn't understand why, with all the data that is available to life science companies. Some of the issues were direct and non-direct issues with supply chain.

Supply Chain Challenges

3 Donal Cronin: What do you perceive as the primary causes of drug supply delays? (Manufacturing, supply chain, regulatory factors?)

Chloe Wilson: There are numerous overlapping issues. Key supply chain-dependent issues include lean manufacturing, unexpected disasters, shortages of quality materials, parallel trading and counterfeit drugs. Supply chain-independent issues include fluctuating demand, economic viability, regulatory delays, quality issues, and cyber security. Quality issues and deviations are significant, often due to manufacturing problems and poor data communication.

4 Donal Cronin: What are the main supply chain challenges in ensuring reliable access to critical medications?

Chloe Wilson: Quality issues and deviations are the most significant challenges, often due to manufacturing problems and poor data communication. Interoperability among different ERP systems is also a major issue.

Manufacturing issues are definitely a major factor, but communication gaps and raw material shortages are also significant. Additionally, there's a lack of interoperability between ERP systems, which causes further complications. Companies are often reluctant to share data in real-time due to concerns over data ownership and potential misuse. There's also a disconnect between regulatory requirements and practical implementation, especially when dealing with multiple jurisdictions.

5 Donal Cronin: To what extent would real-time data access improve availability?

Chloe Wilson: Real-time data access would significantly improve availability by preventing deviations and ensuring proper data communication across the supply chain. It would also help in predicting medicine shortages and improving audit processes.

There is a ripple affect when quality issues are encountered in early stages of the supply chain. Batch data between partner sites is highly complex to integrate. Interoperability is a key issue internally in life science companies. There is an act in the US similar to DSA in EU that requires companies to provide metadata to the regulators but is very complex. The EU has serialisation but this complex also to get to the right level of data.

Perspectives on Blockchain Technology

6 Donal Cronin: Have you heard of blockchain technology before? What is your general understanding of it?

Chloe Wilson: Yes, I'm familiar with blockchain as an immutable ledger that allows data transmission in blocks or hashes. It has potential in the pharma supply chain but faces challenges in standardisation and interoperability.

Most famous for Bitcoin but has been raised in a number of life science working group sessions through @@leading life science industry-wide organisation##. In these discussions questions were often raised on what roles are played, who rolls it out and who manages it. A consortium approach was mentioned a s potential solution.

7 Donal Cronin: What potential benefits could a real-time, transparent data system offer in drug supply?

Chloe Wilson: It would help in predicting stockpiles, preventing medicine shortages, and improving audit processes. It would also reduce quality issues and data decay. Data decay

from legacy systems and interoperability issues could be resolved through Blockchain by having data in a single system.

There is an example of a Swedish group who focused on stockpiling antibiotics. They were able to tell what inventory is in the country and help with reimbursement. Ireland could have much more drug products sitting in the country than what is being told. Access to this information could be hugely beneficial to the healthcare industry. A robust system across internal sites covering the whole supply chain would be massively beneficial.

8 Donal Cronin: Would regulatory and compliance challenges be a concern with blockchain?

Chloe Wilson: Yes, particularly with data security and the high potential risk of quantum computing to break encryption. The system must be rock solid and secure to gain regulatory approval. In its current form Blockchain shouldn't be an issue if standardised and companies cannot see other competitors' data. The HPRA would have to be convinced this is robust and no mistakes. However, they are very slow to act and could focus on areas that are absolutely critical.

Governance and Funding

9 Donal Cronin: Who should be responsible for managing a blockchain-enabled system?

Chloe Wilson: A public-private partnership would be ideal, with funding from both the public and private sectors. The system should be governed by a body similar to the IMVO for serialisation. This was a public-private partnership, funded by the private sector who did have a seat the at board. Big challenge was on who owned the solution. The main outcomes were that you should only see data you input an no one else's and there was little appetite from the life science organisations.

10 Donal Cronin: What roles should stakeholders (government, private companies, regulators) have to ensure transparency, compliance, data quality and reliability?

As above and below.

11 Donal Cronin: How should such a system be funded?

Chloe Wilson: The funding should come from both the public and private sectors, with the government building the infrastructure and the private sector contributing to the costs, potentially through a consortium model with matching funds from the public sector.

Trust and Adoption

12 Donal Cronin: What factors influence your trust in a blockchain-based data sharing system?

Chloe Wilson: The system must be secure, standardised, and interoperable. It should also have robust data encryption to prevent breaches.

13 Donal Cronin: Would the HSE consider adopting a new system if it improves drug availability and transparency?

Chloe Wilson: Yes, the HSE would likely adopt such a system, especially if it integrates with the National Drug Product Catalogue (NDPC) and provides significant benefits in managing drug supplies.

Life science companies would need to do it across EU rather than Ireland to mitigate other countries implementing different solutions.

14. What security concerns do you believe life science organisations would have about sharing real-time manufacturing and supply chain data?

Chloe Wilson: Interoperability challenges and data security concerns are major barriers to adoption. Successful implementation would require strong governance frameworks and reliable systems. Without standardisation and agreement on how data is shared and protected, the system will struggle to gain widespread adoption. Companies need to see the benefits clearly, and there needs to be a mechanism for addressing concerns over data misuse or breaches.

15. How likely is industry-wide adoption of Blockchain systems?

Chloe Wilson: There are two main wholesalers in Ireland that cover about 90% and then the NDPC themselves, so could cover a lot from this approach. Targeting these areas wouldn't address supply chain issues however. Could use serialisation approach if interested in targeting stockpiling issues (IMVO). The solution would need to be EU wide.

Section 8: Incentives & Challenges

16 Donal Cronin: In your opinion, should healthcare procurement processes favour suppliers who can provide real-time access to manufacturing and supply chain data?

Chloe Wilson: Yes absolutely they should be provided. Financial incentives are always effective, but regulatory incentives might be even better. For example, faster approval processes or tax breaks for companies that provide real-time data. Providing companies with practical benefits will be essential to encourage widespread adoption.

Regulation could act as a barrier to entry for smaller companies, however, they likely need to meet certain thresholds to gain market approval anyway. Would definitely support it but would need more research.

17. Donal Cronin: If such a data-sharing mechanism was in place, what incentives, if any, should be provided to life science organisations.

Chloe Wilson: There would need to be a long lead-in time, framework and structure. If HPRA / regulator are mandating it they would need to provide an easy way to integrate with it. Incentives could be to favour compliant companies and provide better rates, making them a preferred supplier. The costs could be recouped through a toll-bridge like approach where they are charged until the costs are covered.

Incentives for wholesalers and healthcare insurance companies such as VHI and Laya would be beneficial. Life science companies are going this route anyway with data integration and interoperability strategies. Faster reimbursements would be beneficial. Pharmacies are quite disbursed in Ireland and this could help. The government would have to be the ones to build it and keep standardised.

18. Donal Cronin: Is there anything else you would like to share around the integration of life science and healthcare industries through Blockchain, to reduce drug shortages?

Chloe Wilson: Pilot studies would be needed and some countries are doing this. Linking the solution to IMVO approach would be beneficial so that everyone is speaking the same language in terms of interoperability, using Blockchain.

Cyber security still a risk, if you integrate the entire supply chain you create a single point of failure. Would need to decentralise it and use firewalls.

The technical considerations should be fine as Blockchain speaks the same language.

There is definite value in this type of solution and other countries could be examined. Life science companies actually see benefits in regulations where they provide value, such as standardisation. Serialisation has value despite it being complex.

Participant: Jane Browne

Date: 2 April 2025, 14:00 pm

Interview Notes:

Section 1: Background & Experience

1. Donal Cronin: To start, could you provide a bit of background on your experience in the healthcare or life sciences sector?

Jane Browne: Sure. I retired about a year and a half ago. Before that, I was the Director of @@leading life science industry-wide organisation##, the main representative body for the pharma, chemical, and biotech industries in Ireland. I founded it for IBEC in 1994. Before that, I worked in the industry manufacturing, including roles at @@numerous large-scale life science organisations##. I have a degree in chemistry, chemical engineering, and an MBA.

I've been involved in various initiatives to improve manufacturing capabilities in Ireland. Working with government agencies and stakeholders to address industry needs was a big part of my role. I've seen firsthand how supply chain disruptions can impact availability.

2. Donal Cronin: With that extensive background, have you encountered or are you aware of drug shortages within healthcare settings, particularly in Ireland?

Jane Browne: Yes, absolutely. My main exposure to shortages was during my work in the European API industry. Interruptions in API supply have been a frequent issue, particularly when supply chains are disrupted. For instance, during the pandemic, Ireland faced shortages of common drugs like Panadol due to disruptions in India and China. These issues highlight the fragility of global supply chains. When something goes wrong, the impact can be felt very quickly, especially in a small market like Ireland. Part of the role was lobbying Ireland to bring back more API production in the country to mitigate issues like India

choosing to close it's borders.

Section 3: Supply Chain Challenges

3. Donal Cronin: What do you perceive as the primary causes of these shortages?

Jane Browne: From my experience, manufacturing delays, particularly in API supply, are the main cause. Ireland's small market size is also a factor. Additionally, when manufacturing moves to countries like India and China, supply chains become even more vulnerable. Dependence on imports and long supply chains mean that any disruption can have a significant impact on availability.

The issue is not just manufacturing. Regulatory approval processes, tariffs, geopolitical instability, and even simple logistical problems can all contribute. There's a need for greater coordination across the supply chain.

Potential solution to the market size problem is looking at group purchasing agreements, such as a recent initiative where Ireland looked to group with Benelux countries to bulk purchase materials.

4. Donal Cronin: What are the main supply chain challenges in ensuring reliable access to critical medications in your opinion

Jane Browne: In addition to manufacturing issues above, the capabilities to store enough product in Ireland is an issue. Storing large volumes of product requires significant cold storage investment. DHL are putting it in place but more warehousing with cold storage capabilities is required.

5. Donal Cronin: To what extent would real-time data access improve availability?

Jane Browne: Absolutely, yes. Data as real-time as possible would be a massive benefit. EY looked at digitising Cell and Gen Therapy processes before. DHL will say that they have systems that could integrate. There is an example in the US where they have an airline booking like system for managing Gene Therapies.

Section 4: Perspectives on Blockchain Technology

6. Donal Cronin: Are you familiar with Blockchain technology, and do you see its potential use in addressing these issues?

Jane Browne: Yes, I am familiar with blockchain as a concept but the inner workings of it. It could enhance data security, traceability, and supply chain transparency. It's particularly useful for preventing counterfeiting and ensuring product authenticity. However, it's important to ensure compatibility with existing systems. I think blockchain could play a role in streamlining data sharing and improving visibility, but only if there's a concerted effort to integrate it effectively.

Blockchain has potential, but it's not a magic bullet. It requires a lot of buy-in from stakeholders, and there's always a risk that companies will be reluctant to share data unless they see a clear benefit.

In the area of counterfeit drugs and poor raw material quality, Hamburg being a freeport to the US is an example of the lack of controls there in the market.

7. Donal Cronin: What potential benefits could a real-time, transparent data system offer in drug supply?

Jane Browne: Counterfeit drugs mitigation. Also knowing where the product is at all times. For example, knowing that there are 50 packs of something in Dublin and 25 in Paris, it would help with fulfilment. Would need strong oversight.

8. Donal Cronin: Survey results highlighted that 44% expressed concerns about 'Regulatory and compliance challenges'. Would this be of concern to you and are there any other challenges you foresee with Blockchain for data-sharing?

Jane Browne: Yes, it would need to be compliant. Needs to meet auditing standards. If it does, it should have real benefits in streamlining the audit processes.

Section 5: Governance & Funding

9. Donal Cronin: Who should manage a blockchain-based system? Public sector, private sector, academia, or a mix?

Jane Browne: I'd recommend a public-private partnership. Commercial data concerns would need to be addressed, but I believe industry funding is feasible if clear agreements on data access are established. The public sector can provide the regulatory framework, but

the private sector needs to be actively involved in implementation. It's about finding a balance between governance and practicality.

10. Donal Cronin: What roles should stakeholders (government, private companies, regulators) have to ensure transparency, compliance, data quality and reliability?

Jane Browne: Regulator would play a huge role for compliance. Healthcare organisations would need to remain compliant with their own procurement policies also.

11. Donal Cronin: How should such a system be funded?

Jane Browne: Who benefits from it should provide some funding for it, so maybe the HSE and industry. Should not be solely private sector. The infrastructure could be funded by industry. An example would be IMVO where organisations paid contributions. Potentially on a per product basis.

Section 6: Trust & Adoption

12. Donal Cronin: What about challenges related to trust and adoption of blockchain technology?

Jane Browne: Data access, especially around commercial sensitivity, would have to do what it says on the tin. Ensuring compatibility with existing systems is essential for widespread adoption. There's also a lot of scepticism around blockchain because of its association with cryptocurrencies. Education and clear communication will be important in overcoming that scepticism.

13. Donal Cronin: In your opinion, would the HSE consider adopting a new system if it improves drug availability and transparency? Why or why not?

Jane Browne: Yes, absolutely. Huge benefits.

14. Donal Cronin: What security concerns do you believe life science organisations would have about sharing real-time manufacturing and supply chain data?

Jane Browne: Cyber security would be significant, particularly in mitigating infiltration at the different stages of the value chain. Counterfeit products in supply chain could impact production down the line. You would ideally like to see a holistic view of all components, including suppliers and ancillary products used in the production process itself (e.g. vials etc.). Annex 1 of the GmP Directive had a lot of debate around manufacturing of sterile

products.

15. Donal Cronin: How likely is industry-wide adoption of Blockchain systems?

Jane Browne: Can see how it would appeal to the industry. There is a big push on data integration now anyway.

Section 7: Value in Data Sharing

16. Donal Cronin In your opinion, should healthcare procurement processes favour suppliers who can provide real-time access to manufacturing and supply chain data?

Jane Browne: Yes, absolutely. Real-time data access would improve availability. However, it's also important to establish compatibility and trust between stakeholders. Without trust, companies will be reluctant to share data, even if it's in their best interest to do so. Demonstrating the value of data sharing will be key.

17. Donal Cronin: What incentives do you think would encourage companies to participate in a blockchain system?

Jane Browne: Financial incentives are a good starting point, but they're not enough. Companies need to see tangible benefits from sharing data. Regulatory incentives, like streamlined approval processes or tax breaks, could be effective. It's also important to address concerns around data security and ownership. Faster reimbursements would be very attractive to life science companies. For example, it takes so long to get reimbursements for Oncology and orphan drug products currently. Quicker approvals for new medicines would be appealing also.

18. Donal Cronin: Are there any other challenges you foresee in the adoption of blockchain technology?

Jane Browne: Apart from the technical challenges, cultural resistance is a major barrier. Companies have been operating in a certain way for years and convincing them to adopt something new isn't easy. There needs to be a concerted effort to demonstrate the value of blockchain and how it can address existing problems more effectively than current systems.

Participant: Emily Davis

Date: 9 April 2025, 16:00 pm

Interview Notes:

Section 1: Background and Context

1. Donal Cronin: Can you describe your current role and experience across the areas of life sciences manufacturing, digital technologies, or data management?

Emily Davis: I've been working in the pharmaceutical industry for almost 25 years, originally as an automation engineer at a manufacturing site. I supported manufacturing equipment and processes, then moved into IT roles supporting manufacturing applications like OEE. More recently, I've been working on data integration—getting data from shop floor systems to ERP systems.

2. Donal Cronin: What exposure have you had to initiatives integrating digital technologies like Blockchain in pharmaceutical manufacturing or distribution?

Emily Davis: I haven't had direct experience using blockchain in pharma manufacturing. I've done some personal research to understand how it could be applied, but I haven't seen it in practice in this domain.

3. Donal Cronin: In your experience, what are the key pain points in end-to-end visibility across pharmaceutical supply chains?

Emily Davis: The key challenge is making data accessible, accurate, and available to everyone across the supply chain. A big issue is the lack of standardised terminology across systems. Data might be locked in legacy systems behind firewalls or use different business terms, making interoperability difficult.

Section 2: Supply Chain & Data Sharing Challenges

4. Donal Cronin: From your perspective, what are the primary root causes of drug shortages in pharma manufacturing?

Emily Davis: From my view, it's production delays—equipment failures, bottlenecks, or

extended downtimes. I don't see much of the raw materials or planning side, but when a critical piece of equipment fails, it causes a domino effect. No visibility an issue.

5. Donal Cronin: What challenges do you see in achieving data interoperability across life sciences manufacturers, distributors, and downstream stakeholders?

Emily Davis: Beyond access issues, the main challenge is the lack of a shared language or standards. Each ecosystem—manufacturers, hospitals, pharmacies—uses its own business terms. That fragmentation complicates interoperability.

6. Donal Cronin: How significant is the lack of real-time or near-real-time data in your view? Would improved visibility influence operational or strategic outcomes?

Emily Davis: It's extremely significant. If we had real-time data, we could catch anomalies early and prevent failures, using predictive and adaptive analytics. That kind of visibility could reduce disruptions and support faster decision-making.

Section 3: Blockchain Technology Perspectives

7. Donal Cronin: What is your understanding or practical experience of Blockchain solutions in manufacturing or other areas?

Emily Davis: I understand the theory—distributed ledgers ensuring secure and immutable records. I haven't seen it used in manufacturing yet, just in cryptocurrency contexts.

8. Donal Cronin: Do you see Blockchain as a viable solution for addressing data fragmentation in the pharma supply chain? Why or why not?

Emily Davis: Yes. In pharma, data is just as important as the drug itself—without the batch record, the product is unsellable. Blockchain could ensure the integrity and traceability of those records. You do two things in drug production – you produce the drug and you create the record of making that drug. Due to validation requirements and regulations, without the data you can't sell the drug.

9. Donal Cronin: What technical or operational challenges do you anticipate in deploying Blockchain solutions at scale across the pharmaceutical ecosystem?

Emily Davis: The inefficiency of blockchain is a big concern—high energy usage, storage, and computing needs. A private blockchain could be more efficient within a single company, while a public ledger may work better across organisations. Because you need a tonne of

different servers it is very inefficient, though that does help with keeping it secure.

Section 4: Standards, Compliance & Governance

10. Donal Cronin: In the context of GmP, how compatible is Blockchain-based traceability with current compliance obligations?

Emily Davis: Right now, validation is a huge cost—we manually test data from sensors to PLC, PLC to SCADA, SCADA to MES, MES to ERP systems. Current validation process is old and outdated. We would need to change the whole validation model. Companies in this industry spend billions of dollars every year in validations. Blockchain could potentially remove that need, which would be transformative. But regulators would need to accept this new model. This would be a strong incentive.

11. Donal Cronin: What challenges do you foresee in aligning Blockchain implementations with global regulatory frameworks?

Emily Davis: Historically, regulators have evolved from rigid validation to more risk-based approaches. That gives hope. But they'll still need solid proof—a pilot or proof of concept—to approve blockchain-based systems.

12. Donal Cronin: Who should ideally own or govern a Blockchain-based supply chain data infrastructure?

Emily Davis: A neutral third party. From my experience with @@large-scale life science manufacturing company's## serialisation project, systems like this shouldn't be owned by individual manufacturers or regulators alone. Neutral governance ensures consistency and trust.

Regulators are slow and more react to changes then proactive when it comes to manufacturing. A consortium, potentially a solution provider who is audited as compliant.

Section 5: Security, Trust & Adoption

13. Donal Cronin: What are the key security concerns associated with sharing manufacturing and supply chain data on a distributed ledger?

Emily Davis: Overall, you would be better secured being on Blockchain then not. The main concern would be commercial visibility—if it's a public ledger, competitors might access sensitive supply chain data.

14. Donal Cronin: From a data integrity and trust perspective, how does Blockchain compare with traditional secure data exchange platforms?

Emily Davis: Blockchain is stronger. It's tamper-proof and transparent, whereas APIs or EDI depend on developers to maintain accuracy and honesty. You can't fake a transaction in Blockchain, API programmers can.

15. Donal Cronin: What factors would most influence industry-wide adoption of Blockchain platforms in pharma manufacturing?

Emily Davis: The ROI is key. Companies won't adopt unless they see cost savings. Validation savings could be a major driver. Regulatory clarity and improving blockchain's technical efficiency are also important. You would need to be able to make it compliant but also efficient. If it is not more efficient, that would be a big negative factor.

Section 6: Value Creation & Incentives

16. Donal Cronin: What potential commercial or operational benefits could manufacturers derive from participating in a transparent, Blockchain-enabled data-sharing network?

Emily Davis: The biggest is reduced validation costs. That alone could save billions annually across the industry.

17. Donal Cronin: Would you support procurement preference for manufacturers who offer real-time data visibility as part of their value proposition? Why or why not?

Emily Davis: Yes. If I were in procurement, I'd prefer visibility into production, traceability, and quality. It builds confidence in the product's authenticity and reliability. You know what you're getting and it's of good quality.

18. Donal Cronin: What types of incentives could help drive wider adoption across the pharma ecosystem?

Emily Davis: Financial, regulatory, and reputational. But also awareness—many don't understand blockchain's value outside of cryptocurrency.

Section 7: Looking Ahead

19. Donal Cronin: Are there any pilots, proofs-of-concept, or Blockchain consortia (e.g., MediLedger, PharmaLedger) you're familiar with or involved in?

Emily Davis: No, I'm not aware of any currently.

20. Donal Cronin: In your opinion, what does an ideal future state for integrated data-sharing across life sciences manufacturing look like?

Emily Davis: A transparent, standardised data model accessible across the entire supply chain. Everyone would speak the same "data language," improving coordination and visibility. All data stored in a common data model that is standardised and available.

21. Is there anything else you'd like to share about the role of Blockchain in enabling next-generation pharma supply chain transformation?

Emily Davis: Just that I believe in the potential, but I don't think enough people are seriously looking into it yet. There's an opportunity here that shouldn't be missed.

Participant: Laura Taylor

Date: 14 April 2025, sent remotely due to time constraints

Question Responses:

Interview Questions

Background and Context

3. Can you describe your background and experience within healthcare or life sciences sector?

   Laura Taylor: Qualified pharmacist with seven years' experience in the community pharmacy environment in a variety of leadership roles including relief, support, supervising and area pharmacist roles. Following additional education, I moved into advisory consulting and have spent the last five years supporting and providing

oversight on a range of health and life sciences projects.

4. In your experience, have you encountered, or are aware of, instances of drug shortages in a healthcare setting?

   Laura Taylor: Yes, I encountered drug shortages on an almost daily basis as part of my role as a community pharmacist. I left the community pharmacy environment in 2020 but I understand the issue has become more pronounced in recent years.

Supply Chain Challenges

The HPRA have previously stated that 60% per cent of reported shortages are related to delays in manufacturing, while 53% of survey respondents identified 'Supply chain disruptions' as a major cause.

6. What do you perceive as the primary causes of drug supply delays? (Manufacturing, supply chain, regulatory factors?)

   Laura Taylor: Yes, I'm not surprised that manufacturing and supply chain are cited as the primary issues. That would be my view too. The size of the Irish market was regularly mentioned as a challenge in my time in community pharmacy also, with pharmaceutical companies prioritising other larger markets for commercials reasons in times of medicine shortages. The HPRA has a strong reputation internationally and have robust systems in place when getting medicines to market safely and effectively. They've also increased recruitment in the medicines shortage space recently so I would say regulatory factors have improved and are no longer a key blocker to medicines accessing the Irish market.

7. What are the main supply chain challenges in ensuring reliable access to critical medications in your opinion? (Procurement practices, real-time data, market size etc.)

   Laura Taylor: Market size would be the key one in my experience. Ireland has a heavy reliance on imports so it's very vulnerable to global supply disruptions, and I think this was acutely seen with the COVID-19 pandemic and ongoing geopolitical tensions with Brexit specifically coming to mind. I have heard cases of

pharmaceutical companies prioritising other countries with more streamlined reimbursement decision making also. I think officially the HSE's Corporate Pharmaceutical Unit (CPU) aim to have a reimbursement decision within 45 days but this is very rarely achieved leading to prolonged delays for pharmaceutical companies in getting their products onto the market. Although, playing devils advocate, I think pharmaceutical companies are often unrealistic with medicine pricing levels initially, which leads to prolonged negotiations with the HSE's CPU until a more reasonable middle ground reimbursement price is found, so this is also contributing to delays in getting medicines to market.

8. To what extent would real-time data access improve availability?

   Laura Taylor: Yes, it would be a useful addition and could by default, provide additional reassurance to patients and healthcare professionals if there was greater transparency from a data viewpoint.

Perspectives on Blockchain Technology

9. Have you heard of Blockchain technology before? If so, what is your general understanding of it?

   Laura Taylor: Yes, essentially a secure system that allows for the movement of information. Not too familiar with the finer details though!

10. What potential benefits could a real-time, transparent data system offer in drug supply?

    Laura Taylor: I assume it could support secure, real-time and I imagine more transparent tracking of information, in this case medicines, as they move through the supply chain, which would allow for better, more informed, decision making.

11. Survey results highlighted that 44% expressed concerns about 'Regulatory and compliance challenges'. Would this be of concern to you and are there any other challenges you foresee with Blockchain for data-sharing?

Laura Taylor: No, as above, I think the HPRA (and other bodies like the IPU) are taking the medicine shortage issue very seriously and are proactively addressing it through a variety of initiatives. Albeit, lots done, more to do.

Blockchain is still a relatively new concept so I would imagine adoption amongst key users could be challenging, cost of the infrastructure, and how it would meet regulatory and legal guidelines.

Governance & Funding

12. Who should be responsible for managing a Blockchain-enabled system? Public sector, Private sector, Academia or Pubic Private Partnerships?

    Laura Taylor: Unless there's a very strong business case that would clearly highlight the benefits of implementation, I would imagine it would be unlikely that the public sector would lead the push for a blockchain enabled system. I think HSE or HPRA would more likely want to sit it working efficiently (taking into account their risk averse approach) before taking a gamble to engage with this approach, I imagine a private sector, potentially with academia involvement, would be the most likely cohort that would take responsibility.

13. What roles should stakeholders (government, private companies, regulators) have to ensure transparency, compliance, data quality and reliability?

    Laura Taylor: Government agencies would need to establish robust frameworks and legal guidelines to support, likely reflecting on national and international standards.

    Private companies would need to drive early adoption and implementation by investing heavily in the technical infrastructure. They would need to collaborate with supplier, distributors and partners.

    Regulators would need to ensuring compliance to appropriate standards, the areas of data protection comes to mind as a key area.

14. How should such a system be funded?

Laura Taylor: Realistically, private sector is the likely option.

Trust & Adoption

12. What factors influence your trust in a Blockchain-based data-sharing system?

    Laura Taylor: The security of the system, how transparent it is, level of privacy incorporated and the overall performance and scalability.

13. In your opinion, would the HSE consider adopting a new system if it improves drug availability and transparency? Why or why not?

    Laura Taylor: I think if it is adopted and successful elsewhere (either privately in Ireland, or internationally) and has a clear business case on how it would save the tax payer money, I would like to think the HSE would consider adoption. I think the HSE is a very reactive and risk averse organisation, so they likely wouldn't be proactive enough or have the vision to engage themselves without a clear business case to reflect against.

14. What security concerns do you believe life science organisations would have about sharing real-time manufacturing and supply chain data?]

    Laura Taylor: I imagine they would be concerned about privacy primarily, as fundamentally their supply chain data is very commercially sensitive information. Pharmaceutical companies are also highly focused on regulatory requirements and compliance to standards, so ensuring compliance with appropriate laws and regulations would be another key security factor.

15. How likely is industry-wide adoption of Blockchain systems?

    Laura Taylor: It will happen, but probably more medium term that short term. We've seen with how long it took crypto currency to be taken seriously!

Value in data sharing

16. In your opinion, should healthcare procurement processes favour suppliers who can provide real-time access to manufacturing and supply chain data?

    Laura Taylor: Yes! As real time data brings so many additional advantages…first and most importantly, enhanced patient safety which is a healthcare professionals primary concern. Then additionally, improved efficiency, likely cost reduction, better decision making etc

17. If such a data-sharing mechanism was in place, what incentives, if any, should be provided to life science organisations.

    Laura Taylor: I think the incentive for life sciences companies will come from the benefits of implementation i.e. greater efficiencies, lower costs, and not from any other bodies incentivising

Conclusion

18. Is there anything else you would like to share around the integration of life science and healthcare industries through Blockchain, to reduce drug shortages?

    Laura Taylor: It's clear that blockchain technology, on paper, has the potential to have a positive effect on the life sciences and healthcare industries but addressing the key challenges / hesitations for its usage will be key in ensuring that it adoption will be seen sooner rather than later!

E. Example Survey Questionnaire

An Example Survey Questionnaire was prepared during the Methodology development phase of this research project before being finalised in the Primary Research phase, and can be seen below.

Section 1: Demographic & Industry Background

1. What sector are you most familiar with in your career? *(Select one)*
    - Healthcare
    - Life Sciences (e.g. Pharma, Biopharma, Medical Device, MedTech)
    - Pharmacy
    - Supply Chain/Logistics
    - Industry body (Life Sciences)
    - Industry body (Healthcare)
    - Public sector
    - Other (please specify) _____
2. What type of organisations do you work most closely with?
    - Public healthcare system (HSE)
    - Private hospital or healthcare provider
    - Life Science manufacturing & supply chain
    - Life Science commercial
    - Supply chain/logistics company
    - Other (please specify) _____
3. What area of expertise describes your background most accurately?
    - Technology
    - Business support
    - Strategy development
    - Commercials
    - Procurement

4. How many years of experience do you have in working with your chosen sector?
    - 0–2 years
    - 3–5 years
    - 6–10 years
    - More than 10 years

Section 2: Awareness & Perception of Drug Shortages

5. Are you aware of drug shortages in the Irish healthcare system?
    - Yes
    - No
6. If yes, how frequently do you perceive there to be drug shortages?
    - Rarely (less than once per quarter)
    - Occasionally (every few months)
    - Frequently (monthly)
    - Very Frequently (weekly or more)
7. In your opinion, which categories of drugs are most affected by shortages? *(Select all that apply)*
    - Oncology
    - Neurology
    - Diabetes
    - Cardiovascular
    - Pain management
    - Other (please specify) _____
8. How would you describe the nature of drug shortages?
    - Seasonal
    - Predictable
    - Unpredictable
    - Constant
9. How significant is the impact of drug shortages on patient care, in your opinion? *(Scale 1–5: 1 = No Impact, 5 = Severe Impact)*
    - 1 | 2 | 3 | 4 | 5

Section 3: Causes & Supply Chain Transparency

10. In your opinion, what are the primary causes of drug shortages in Ireland? *(Select up to 3 and rank)*
    - Manufacturing delays
    - Supply chain disruptions (logistics)
    - Regulatory compliance issues
    - Lack of data transparency
    - Procurement inefficiencies

- Stockpiling behaviours
- Market size
- Other (please specify) _____

11. To what extent would you agree with the statement that greater transparency in pharmaceutical supply chains help mitigate shortages?

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

12. To what extent would you agree with the statement that improved healthcare procurement processes and incentives are needed to mitigate shortages?

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

13. Do you believe pharmaceutical manufacturers should be required to provide real-time supply chain data to healthcare providers?

- Yes
- No
- Unsure

Section 4: Blockchain as a Potential Solution

14. How familiar are you with Blockchain technology?

- Not at all familiar
- Somewhat familiar
- Familiar
- Very familiar

15. Blockchain technology allows for immutable, secure, and transparent data sharing. Would organisations in your area of expertise be open to using Blockchain for supply chain visibility in healthcare procurement?

- Strongly agree
- Agree
- Neutral
- Disagree

- Strongly disagree

16. What do you believe would be the greatest benefits of a Blockchain-enabled supply chain? *(Select up to 3)*

- Reduced drug shortages
- Improved regulatory compliance
- Enhanced traceability & tracking
- Faster response to supply chain disruptions
- Cost reductions in procurement
- Increased trust between manufacturers & healthcare providers
- Other (please specify) _____

17. What concerns, if any, would prevent you from adopting Blockchain for drug supply chains? *(Select all that apply)*

- Cost of implementation
- Regulatory and compliance concerns
- Data security/privacy risks
- Complexity of integration with existing systems
- Lack of industry-wide adoption
- Public perception
- Other (please specify) _____

18. Do you believe there would be benefits in a bi-directional data-sharing model where healthcare procurement data (e.g., forecasted demand) is securely shared with pharmaceutical manufacturers to optimise supply chain management?

- Yes
- No
- Unsure

Section 5: Governance & Industry Adoption

19. Who, in your opinion, should be responsible for governing a Blockchain-enabled drug supply chain system?

- Government/Public Health Authorities (e.g. HSE, HPRA, NDMP)
- Private Industry (Pharmaceutical companies)
- Industry Consortium (Public-private partnership)
- Other (please specify) _____

20. How should such a Blockchain system be funded?

- Public sector (HSE/government)
- Private sector (pharmaceutical companies)

- Consortium model (joint funding)
- Other (please specify) _____

21. Would the availability of transparent, real-time supply chain data influence procurement decisions toward pharmaceutical companies who can provide it, in your opinion?

- Yes, I believe suppliers with transparent data-sharing should be prioritised
- No, cost and availability remain the primary factors
- Unsure

22. To what extent would you agree with the statement, that prioritising procurement from pharmaceutical companies that provide full transparency via Blockchain, should be done, even if at a slightly higher cost?

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

Section 6: Final Thoughts

23. Overall, do you believe Blockchain-enabled data-sharing could help reduce drug shortages in Ireland?

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

24. Are there any additional comments or concerns you would like to share about drug shortages, manufacturing operations, supply chain transparency, or Blockchain adoption? *(Free text)*

F. Ethics Declaration Form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: Use of Blockchain Technology in reducing drug supply shortages in the Irish public healthcare system through cross-industry data-sharing of pharmaceutical manufacturing and supply chain data.

RESEARCHER'S NAME: Donal Cronin

PROGRAMME OF STUDY: Digital Transformation (Life Science)

SUPERVISOR'S NAME: Dr Diarmuid O'Briain

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:
STUDENT SIGNATURE: Donal Cronin

DATE: 1 December 2024

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE: Diarmuid Ó Briain

DATE: 1 December 2024

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 **Purpose and objectives of research**

The key aim of this research paper is to examine if Blockchain Technology can be used to facilitate timely and transparent sharing of manufacturing and supply chain data to reduce shortages in supply of life-changing drugs to patients within Ireland's Health Service Executive (HSE) system. This will be viewed specifically from the perspective of integrating private Life Science organisations with the Irish public healthcare system, to trace all steps involved in the production and distribution of drug products to healthcare providers. The evaluation of Blockchain will be limited to the identification and assessment of challenges in data integration and will not include a case study or full technical feasibility study of the technology itself.

Objectives

1. Identify current challenges with supply chain data access for high demand drugs in Ireland's healthcare system.
2. Evaluate the benefits of Blockchain in sharing of data related to critical drugs across manufacturing and healthcare organisations.
3. Identify and assess the technical challenges of integrating data with Blockchain.
4. Determine qualitative demand for sharing of manufacturing & supply chain data (seller) and drug administration data (buyer).
5. Determine the feasibility of adopting Blockchain technology to reduce drug supply shortages.

1.2 Research methodology: *[300 words maximum/ detail how you will acquire your primary data (focus groups/interviews/online surveys etc). Proposed questions for questionnaires and/or interviews must be included in the appendix].*

The study adopts an interpretivist philosophy, emphasising stakeholders' perspectives in healthcare and pharmaceutical supply chains. Using an inductive approach, it will derive themes and theories directly from qualitative data. A mixed-methods design will integrate qualitative interviews and surveys, complemented by quantitative insights from tools like Likert and Linear Numeric scales. This approach aims to provide a holistic understanding of stakeholder needs, challenges, and perceptions about Blockchain-enabled data-sharing.

Data Collection Methods

1. **Surveys (Quantitative and Qualitative Data)**
   Surveys will assess demand for cross-industry data-sharing and explore attitudes toward Blockchain in drug supply chains and public healthcare.

   - **Design**: Questions will combine qualitative insights and quantitative measures, focusing on trust in Blockchain, data privacy concerns, and the value of cross-sector data-sharing.
   - **Participants**: Stakeholders in manufacturing, procurement, logistics, and distribution from Life Science organisations, as well as regulatory bodies like the HSE, HPRA, and NDMP.

2. **Stakeholder Interviews (Qualitative Data)**
   In-depth interviews will provide deeper insights into supply chain challenges, technical considerations for Blockchain integration, and stakeholder views on feasibility and benefits.

   - **Participants**: Selected based on survey engagement, with additional participants identified through survey responses.
   - **Topics**: Focused on supply chain challenges, data-sharing value, and Blockchain integration feasibility.
   - **Preparation**: Tailored question packs will be shared in advance to clarify survey responses and explore gaps.

This mixed-methods approach will uncover stakeholder perceptions and challenges, guiding the development of Blockchain-based solutions for improving data-sharing in healthcare and pharmaceutical supply chains.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:	
Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:	
People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study *[Do not provide names except where it is deemed impossible to conceal identity].*

- Surveys participants will be selected from manufacturing and supply chain areas of Life Science organisations; identified through contacts and networks of senior colleagues in the current workplace (Grant Thornton) and industry body groups, such as the IPHA and BPCI.
    - Participants from these areas will aide the objectives of this research by providing key insights into technical challenges associated with integrating operations data with Blockchain, the value (if any) in achieving this, as well as perceptions on Blockchain technology within the industry.
- Representatives from healthcare procurement, regulatory, logistics and distribution areas, mainly from organisations such as the Health Service Executive (HSE), Health Product Regulatory Authority (HPRA),

and the National Drug Management Programmes (NDMP) will be selected to take part in the primary research surveys and interviews.

- Participants in these areas will be able to offer valuable insights into the current challenges in supplying drugs in Ireland, extent of drug shortages, the benefits (if any) an integrated supply chain using Blockchain may achieve. They will also have relevant experience working within the boundaries of existing policies, regulations, and organisational processes to inform on the feasibility of such an approach.

4.2 How do you plan to gain access to/contact/approach your participant(s).

Participants will be identified through professional networks. These networks include current employer relationships within Grant Thornton, including Grant Thornton colleagues, and contacts of colleagues within the Healthcare and Life Science industries which will be leveraged for introductions.

Contacts within industry bodies will also be approached for participation, including the Irish Pharmaceutical Healthcare Association (IPHA), Biopharma Chem Ireland (BPCI).

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes No
Details of what participation will involve	Yes No
Rights to anonymity	Yes No
Confidentiality	Yes No
Rights to withdraw from the research	Yes No
The contact details of the researcher and supervisor (if necessary)	Yes No

5.2 **Informed Consent Form (ICF) for participants**

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data as long as it is still useful and there is an intention to use it further for research so if this is not the case then this can be stipulated here and a shorter retention period given.]

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Data will be stored in accordance with GDPR laws. Data pertaining to online surveys, interviews and ICFs will be stored on Moodle within the primary data folder until the research paper has been completed and there is no further need for the data. Online survey data will be removed from the surveying tool on completion of the paper.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	N/A
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	N/A
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:
STUDENT SIGNATURE: Donal Cronin

DATE: 1 December 2024

SECTION 10: APPENDIX

End of document.