Developing Guidelines for the Implementation of Digitalised Technology in Pharmacy

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Dedicated to

My parents, Michael & Yvonne and grandparents Rocco & Josephine,

for their unconditional love, guidance and support.

Thank you

Abstract

The pharmaceutical industry is undergoing rapid digital transformation, driven by technological advancements and the need for improved patient care. This study aimed to identify the key risks and opportunities associated with digitalisation across various pharmaceutical ecosystems, including community pharmacy, hospital pharmacy, regulatory affairs, the pharmaceutical industry and clinical practice. The study also aimed to develop guidelines for pharma digitalisation risk reduction.

The study involved three main phases. Phase 1 involved a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis conducted via semi-structured interviews with thirty different stakeholders, representing the five previously mentioned sectors. Phase 2 involved a focus group with five different stakeholders, one from each sector, to evaluate identified threats using a 5x5 risk matrix. Threats were rated based on probability and severity and average Risk Priority Numbers (RPNs) were calculated to prioritise risks. Risk mitigation strategies were proposed, which served as basis for phase 3 of the study involving guideline development.

Phase 1 identified numerous benefits of digitalisation, including environmental sustainability (n=30), enhanced communication (n=28), optimisation of resources to enhance efficiency (n=22) and error reduction (n=16). Opportunities identified include artificial intelligence introduction (n=25) and automation (n=22) across different pharmaceutical sectors and the development of a centralised digital healthcare system (n=20). Phase 2 identified several risks such as cybersecurity

receiving the highest average RPN score (13.8) during the focus group, followed by regulatory challenges (11.6) and time or training burdens (11.4). Risk mitigation strategies proposed by the focus group participants were used during Phase 3 of this study to develop guidelines. Mitigation strategies suggested included improved IT infrastructure, regulatory updates, staff training and utilisation of user-friendly systems.

The study concludes that while digitalisation presents several strengths and opportunities for pharmaceutical innovation, effective implementation requires addressing the associated risks and weaknesses through targeted mitigation strategies. The resulting guidelines developed offer evidence-based, sector-specific recommendations to evaluate the need for digital advancement and support the safe and efficient digital introduction. These guidelines are intended to guide stakeholders, policymakers and institutions in decision making regarding digital integration to ensure technological advancements align with patient safety, data security and regulatory compliance.

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List of Abbreviations

AI	Artificial Intelligence
AR	Augmented Reality
DHT	Digital Health Tool
e-prescribing	Electronic Prescribing
GDPR	General Data Protection Regulation
IT	Information Technology
ML	Machine Learning
PGHD	Patient Generated Health Data
PI	Pharmaceutical Industry
R&D	Research and Development
RPN	Risk Prioritisation Number
SWOT	Strengths, Weaknesses, Opportunities and Threats
VR	Virtual Reality

Chapter 1 Introduction

1.1 Understanding Digitalisation in the Pharmaceutical Sector

Digitalisation is a term used to describe the integration of technology or digital alternatives as a form of development or transformation in business processes, operational frameworks and service models (Sackey et al, 2024). Digital transformation often involves rethinking organisational culture, employee roles and data governance strategies to ensure sustainable adoption. It is not simply the introduction of computers or software, but a strategic remap of workflows to exploit the full potential of digitalisation and achieve improved healthcare delivery (Karamagi et al, 2022).

Digitalisation provided newly evolved models and introduced opportunities that replace or complement manual or physical tasks, thereby giving rise to a new wave of smart technology (Reis et al, 2019). Digitalisation allows companies to leverage predictive analytics, real-time monitoring, advanced technologies and automation to identify inefficiencies and potential risks at early stages. It involves the utilisation of innovative tools and new sources of opportunities to create additional value and improve efficiency, while also enabling organisations to remain competitive in rapidly evolving markets, in search of modernisation (Gong et al, 2021).

1.2 Impact of Digitalisation on Pharmaceutical Healthcare

Modern technology is implementing changes to both the healthcare and consumer aspect of pharmaceutics (Thacharodi et al, 2024). Through digitalisation, major changes and improvements have also been implemented in the healthcare industry, involving community pharmacies, clinical pharmacies and physicians. It is widely

recognised as a key step for further growth and advancements in patient care and operational efficiency (Kraus et al, 2021).

Technological advancements have promoted electronic health and improved clinical decision support systems which enables real-time data sharing between healthcare providers (Fadahunsi et al, 2022). This involves the incorporation of digital record keeping, electronic prescriptions, telemedicine and telehealth, wearable devices as well as mobile applications (Abernethy et al, 2022).

Blockchain technologies are increasingly being explored to enhance data security and integrity, ensuring patient information remains confidential and tamper-proof. Digital advancements in pharmaceutical settings are considered essential to drive improvement in both the quality and the standard of healthcare experience (Zwack et al, 2023). The adoption of cloud computing and integrated healthcare systems also enables more seamless collaboration across multiple stakeholders, from drug manufacturers to frontline healthcare providers. Technology must be used to improve efficiency, quality and time at which products are manufactured, tested and dispensed (Rathore et al, 2010).

Applying the use of digitalisation in the pharmaceutical sector is still in its early stages, despite several introductions across different countries (Hole et al, 2021). Business owners in this field are faced with broad opportunities aiding them to adhere to the pace of change. One must consider the different risks and opportunities of changing with the new era and determine the necessary adaptations required (Kumar et al, 2020).

1.3 Patient-Centred Digitalisation

Digitalisation has also facilitated a patient-centred approach by promoting personalised treatment plans and enabling timely interventions through continuous monitoring (Thirumal et al, 2024). Through the development of healthcare software, patients can place orders, book appointments and keep track of medical records on any device, maintaining organisation. It is evident that technology has made patient's life faster, easier and more convenient (Palmier-Claus et al, 2013).

Advancements have also played a key role in enhancing patient empowerment by improving access to health information, medical data and monitoring tools (Fitzpatrick, 2023). Digital health education platforms and artificial intelligence (AI) driven symptom checkers further enable patients to understand their conditions proactively and seek timely interventions. Patients are becoming more informed and engage further in their treatment plans, while also increasing their knowledge on the condition (Andersen and Carlsen, 2024).

It is undeniable that patients now have unlimited access to health information, guiding them and directing their lifestyle towards a healthier way (Breeman et al, 2021). Digitalisation and technology have also transformed pharmacist's role by automating processes such as drug interaction checking, digitising patient records and tracking of drug dispensing, which enhances both productivity and efficiency. Despite these gains, technological innovation has shown only limited effect on pharmacists in the clinical setting (Zhang, 2022).

1.4 Industrial Applications of Digitalisation

In the Pharmaceutical Industry (PI), this extends beyond simple automation to include robotics and advanced interconnected systems, allowing for more efficient and cost-effective opportunities (Hole et al, 2021). These tools optimise production by reducing costs, enhance quality control and improve process transparency through data analytics and real-time monitoring (Keliang, 2025).

The use of enterprise resource planning systems plays a critical role in streamlining complex operations by integrating core functions such as production, inventory and quality control (Elragal and Haddara, 2012). Their implementation not only enhances operational efficiency but also supports compliance with good manufacturing practices, enables traceability and improves data management (Feng and Ali, 2024; Zaman, 2024).

Predictive maintenance enabled by digital systems help prevent costly downtime in manufacturing plants and ensures consistent production quality (Van Dinter et al, 2022). Companies in the PI have also incorporated customer relationship management tools, to improve engagement and communication with patients and healthcare professionals, thus aiming to bridge the gap between the patient-centred and the industrial side of pharma (Baashar et al, 2020).

1.5 Digitalisation in Research and Development

Technology must be used to improve efficiency, quality and the speed at which products are manufactured, tested and dispensed (Rathore et al, 2010). Using digitalisation, the Research and Development (R&D) process and clinical trials are facilitated. This is done through accelerated dataset analysis and screening, improving time-to-market for new drugs (Rajora, 2022).

Digitalisation not only speeds up drug discovery but also allows for the simultaneous management and screening of vast, complex datasets which allow researchers to identify viable drug candidates with higher precision and reduced risk of failures during later stages of drug development (Fu & Chen, 2025). This process is further accelerated by leveraging the use of advanced digital introductions such as AI, Machine Learning (ML) and advanced computational tools which aid drug design and predict molecular interactions, as well as toxicology outcomes (Kasoju et al, 2023).

Frequent updates in ML models result in system improvement and adaptation over time, refining their predictive accuracy based on new experimental data, which creates a feedback loop, continuously improving drug development accuracy and efficiency (Serrano et al, 2024). Digital twin models are increasingly used to simulate drug reactions and trial outcomes in virtual environments before clinical testing, reducing costs and ethical concerns (Visan et al, 2024).

Digitalisation also supports the shift towards personalised medicine, where genomic, proteomic and metabolomic data can be integrated into the R&D process to design tailor-made treatments to individual patient profiles, therefore minimising side-effects and improving clinical outcomes (Lee, 2010). Genomic sequencing, biomarker analysis and advanced data analytics are amongst the most common technologies used for such processes (Collins & Varmus, 2015).

Such precision-based approaches are facilitated by bioinformatic tools and cloud-based computing, which allow global collaboration between researchers in real time, regardless of geographical boundaries (Horgan, 2018). Personalised medicine offers promising solutions to address suboptimal medication use and also manages medication adherence and compliance (Hein et al, 2020). In the future, integration of AI-driven predictive models with patient electronic health records may enable truly individualised therapies, transforming preventive and therapeutic care (Hirani et al, 2024).

1.6 The Impact of COVID-19 on Accelerated Digital Introduction

The COVID-19 pandemic had both positive and negative effects on research, with some studies delayed or cancelled due to restrictions (Tirivangani et al, 2021). The pandemic accelerated the adoption of digital health solutions, prompting a surge in telemedicine and remote care research (Labrique et al, 2018). Changes to the pharma sector and accelerated trends forced by the COVID-19 pandemic have shown the importance of using digitalisation as an advantage towards a better future (Horgan, 2020), with many changes made during COVID-19 proving beneficial for

use even after the pandemic (Priyono et al, 2020). This global shift highlights how the pandemic acted as a catalyst for digital health adoption, with researchers and healthcare providers adapting quickly to meet evolving healthcare demands (Abul-Husn & Kenny, 2019).

Virtual consultations and telehealth were available prior to the pandemic, however these were rarely used (Keesara et al, 2020). These technologies were widely adopted during the pandemic and continue to be widely used today. The benefits of these solutions, such as the reduced need for in-person visits, saving time, streamlining access to healthcare services and easing the burden on healthcare workers by decreasing emergency room visits remain highly valuable (Mann et al, 2020).

The COVID-19 pandemic highlighted the role of digital tools in supporting public health measures, such as monitoring disease spread, managing hospital capacity and coordinating patient referrals (Ezenwaji et al, 2024). The transition to digital platforms reduces issues related to travel, hospital parking and waiting times, while also supporting earlier detection of conditions (Kumar et al, 2013; Antoniades et al, 2021).

Big Data, which involves collecting and analysing vast and complex sets of health information, was initially used to trace and diagnose COVID-19 infections (Awotunde et al, 2022). It also facilitated predictive modelling of virus transmission, resource allocation and identification of high-risk populations, which informed public health decisions (Glauner et al, 2021). Mobile applications

leveraged big data technology to store COVID-19 swab test results and vaccination information, allowing international access and recognition whilst also sending notifications for contact tracing and test results to help manage the spread of the virus efficiently (Skoll et al, 2020).

Digital health has further enhanced communication between healthcare professionals and patients, improving care coordination, patient engagement and overall satisfaction (Frederix et al, 2019). The pandemic accelerated the development and integration of digital platforms for patient education, symptom tracking and chronic disease management, demonstrating the value of digital tools beyond acute care. This increased reliance on digital tools during the pandemic highlights how healthcare optimisation through technology can inform and guide future practitioners (Mahajan et al, 2020).

1.7 Threats and Challenges of Pharma Digitalisation

Digitalisation is a fundamental aspect for the future of the pharmaceutical sector and the demand for better and more modern technological advancements brings about its own challenges (Ferri et al, 2020). Many of these challenges arise due to the lack of information or reduced clarity regarding the use of new technology. For example, stakeholders may be unsure about how new digital systems integrate with existing processes or the potential benefits they provide, leading to hesitation or misalignment in strategy (Hoblos et al, 2024).

Common challenges to digital implementation include cyberthreats and data protection, with concerns over hacking, data breaches or data losses (Gebremeskel et al, 2023). Financial pressures also represent a major barrier, as the introduction of new systems often requires substantial investment in software, hardware and workforce training. Infrastructural issues, including reliable connectivity and continuity of power supply, can further complicate implementation, particularly in smaller health systems where resources may be limited (Iyanna et al, 2022). Addressing these challenges is therefore essential to ensure that the benefits of digitalisation are realised without compromising security, sustainability or equity of access (Goel et al, 2024).

Cybersecurity and Data Protection

Cybersecurity threats and hacking may lead to the breaching of data and patients' personal information which increases fear regarding the development of online systems (Seh et al, 2020). As healthcare data becomes increasingly digitised, the potential impact of a single security breach extends beyond financial loss to include compromised patient safety, regulatory breaches or penalties and damage to institutional trust. Cyber threats are not only posed by external hackers but also from insiders such as contractors and employees who have access to sensitive information (Roberts, 2014).

The increasing sophistication of cyber-attacks, including ransomware targeting hospital and patient databases, poses a significant risk to both patient safety and organisational reputation (Joy et al, 2024; Triplett et al, 2024). Furthermore, phishing schemes, malware and unsecured cloud storage further compound these

risks, highlighting the need for continuous monitoring, staff training and robust encryption protocols (Yan et al, 2025).

The production of fraudulent products through better and improved technology used by fake manufacturers is also challenging for the PI (Feeney et al, 2024). Counterfeit medicines can infiltrate the supply chain more easily if robust verification mechanisms are not in place, posing a threat to the healthcare system. Without robust verification mechanisms, such as blockchain-based supply chain tracking or advanced serialisation technologies, these threats remain significant to public health (Zeng et al, 2024).

Financial Barriers

Modern technology often entails substantial upfront and ongoing expenditure making it is expensive for business owners to invest in new technology (Graham, 2024). This financial barrier can slow down innovation, particularly for small and medium sized enterprises that lack the resources of large pharmaceutical corporations. Strategic investment is acknowledged as an essential driver for evolution within the pharmaceutical space (Arendt, 2008; Suresh & Basu, 2008).

Upon implementation of a new system, initial and upkeep investment is seen as a barrier (Ashiwaju et al, 2023). This includes expenses related to software licensing, hardware procurement, staff training and internet technology support services. Small sized enterprises may struggle to allocate sufficient budget for digital transformation without external funding or partnerships (Faridi et al, 2020).

In the cases of system introduction such as Electronic Prescribing (e-prescribing), any fees incurred for implementing or maintaining the system will be indirectly passed along to patients by increasing product cost (Lanham et al, 2016). Patients from lower-income backgrounds may therefore experience disparities in access to digital services, exacerbating existing inequalities. Financial burdens are not only a challenge for stakeholders or business owners but also for end users such as patients. Patients come from diverse backgrounds and not all individuals can cover the costs of digital technology which includes hardware such as mobile phones, a stable internet connection as well as 'in-app' purchases or subscriptions (Choy et al, 2024).

In such contexts, high costs of stable connections or network service are often compounded by inadequate funding and limited accessibility (Odekunle et al, 2017). Maintenance cost, monthly fees for service or data usage or service charges may also be a financial burden to the patient, resulting in a delayed implementation process for digitalisation (Lander et al, 2013).

Infrastructure Limitations

In a patient-centred scenario, telecommunication may pose challenges such as lack of access or errors in transmission which may have harmful effects on the patient due to incomplete or incorrect data transfer (Raeisi et al, 2019). Reliable infrastructure is therefore critical to ensure that digital interventions do not inadvertently introduce new risks to patient care. Access to technology is the first step for digital introduction which is linked to socioeconomic status since not all

patients have access to hardware such as smartphones or computers (Western et al, 2025).

In regions with poor infrastructure, unreliable power sourcing and intermittent internet access further deprive individuals from digital health (Mensah, 2023a; Mensah, 2023b). Khan et al, (2025) reported that in Ghana, poor internet connectivity and unstable electricity hindered e-pharmacy adoption, highlighting the real-world impact of infrastructure gaps. In such situations, digitalisation may deepen rather than close existing gaps in access to medication for certain populations (Saeed, 2021; Badr et al, 2024).

Several digital interventions have failed to improve the healthcare experience because of digital division, where users have unequal access to technology or gaps in digital literacy (Western et al, 2025). This is commonly referred to as the 'digital health divide' and is based on three main barriers: unequal access to digital technology or infrastructure, digital literacy or skills and differences in health outcomes despite having digital access or literacy (Cornejo Müller et al, 2020).

Benefits are skewed towards privileged groups, leaving socioeconomically disadvantaged populations faced with risks related to privacy breaches, data misuse or bias (Iyamu et al, 2022). Szinay et al (2023) reported that digital weight-loss programmes appear to yield greater benefits for younger, urban residents in higher skilled occupations, while older adults and individuals in lower skilled jobs or rural settings may derive fewer advantages (Clougherty et al, 2010; Strulik, 2022).

Patient technological literacy as well as socioeconomic factors may have an impact on such methods of communication (Mahajan et al, 2020). Evidence from multiple studies indicates that people with lower education or income levels, older age, different ethnic backgrounds or rural residency are less likely to engage with digital health tools, even though consistent use is essential for their effectiveness (Chesser et al, 2016; Chae, 2018; Rodgers et al, 2019).

1.8 Strengths and Opportunities of Pharma Digitalisation

Digitalisation is creating new opportunities in the pharmaceutical sector, which extends across different level of practice (Almeman, 2024). This includes AI, automation, the use of interoperable systems to digital outreach, personalised health tools, technology and enhanced manufacturing. These advancements are reshaping how medications are produced, distributed and managed. New innovations, including smart devices and immersive technologies, further highlighting the potential of digitalisation to create a more efficient, transparent and patient-centred healthcare model (Junaid et al, 2022).

Operational Enhancement in Pharma

In the PI, there are also several key opportunities including improved manufacturing intelligence, greater process transparency, introduction of modern machinery and robotics, improved systems of traceability, enhanced real-time monitoring, collaboration and more efficient packaging solutions (Ma et al, 2022). The use of technology not only improves the quality of the products but also cuts down costing while reducing manual labour, thus minimising the risks of errors

whilst achieving faster results with improved repeatability (Piercy & Gist-Mackey, 2021). Digitalisation accelerates processes and reduces labour requirements using robotic control and AI support (Kulkov, 2021).

Robotic introduction does not negatively impact healthcare workers' careers, but instead removes tedious, less meaningful tasks for such machinery, allowing workers to apply their knowledge and skills in more crucial roles (Piercy & Gist-Mackey, 2021). This shift in responsibilities enables personnel to focus on tasks requiring human judgment, such as problem-solving, patient interactions and clinical decision-making. Workers in the pharmaceutical field should serve as points of reference for patients, performing tasks that cannot be fully robotised. It is crucial to note that while automation supports efficiency, it complements rather than replaces lab analysts, lab technicians or pharmacists, who continue to provide expertise and oversight (Sætra & Fosch-Villaronga, 2021).

Unified Systems and Interoperable Pharma Ecosystem

The pharmaceutical field also allows partnerships with major tech giants offering profitable opportunities (Henstock, 2021). Collaborations with technology providers can enable access to advanced analytics, AI models and secure cloud platforms that individual organizations may struggle to implement independently. One of the major goals for transformation includes the formation of an integrated system with applications both in the community and in the industrial sectors. Both cloud technology and blockchain show a strong presence in the pharmaceutical industry. Cloud computing provides a flexible way to store and manage large

volumes of data, making it easier for teams across different locations to access information and work together in real time (Reinhardt et al, 2020).

Blockchain, in contrast, offers a secure and tamper-resistant record of transactions or data exchanges, which can help ensure transparency, protect sensitive information and maintain traceability throughout the pharmaceutical supply chain or during clinical trials (Omar et al, 2021). By implementing blockchain, organizations can also reduce the risk of counterfeit drugs entering the supply chain and improve accountability for each step in production and distribution (Islam & Islam, 2024).

Through the use of technology, different countries seek to find a system through which different workers in the pharmaceutical sector can communicate and share relevant results and information through an interconnected network (Barata et al, 2021). In a study by Tolley et al (2023) stakeholders taking part in semi-structured interviews envisioned a single, centralized and securely coded medication record, accessible by all health and care professionals tailored to their specific roles. Such unified systems facilitate better care coordination, prevent medication errors and support research by providing aggregated and anonymized patient data. This unified system would track a patient's prescribing history across all organizations, optimising care, reducing risks of overprescribing and improving patient safety (Pesel et al, 2022).

Digital Outreach and Remote Engagement

Digitalisation extends beyond pharmaceutical manufacturing and clinical practice into sales, marketing and patient engagement (Bharskar & Siddheshwar, 2020). It also allows pharmacies to strengthen patient relationships by offering digital consultations, automated reminders for medication adherence and educational content. Community pharmacies can create websites, online stores or social media pages where patients can scan prescriptions, order medications, contact pharmacists and gather product information (Alwon et al, 2015).

The growth of online pharmacies has expanded significantly, both locally and internationally, with accelerated expansion forced by the COVID-19 pandemic (Fittler et al, 2024). This provides patients with greater convenience, improved accessibility and health security particularly for those at higher risk of infection. Online stores also benefit owners by reducing operational costs, such as upkeep, maintenance and staff salaries, which can in turn lower the prices healthcare products (Wahl et al, 2024). Digital outreach can improve patient engagement metrics by tracking user interactions, allowing pharmacies to provide more personalised services (Dada & Adekola, 2024).

Advanced Digital Health Tools and AI Applications

Patient Generated Health Data (PGHD) refers to information gathered by patients themselves, using digital health technologies such as wearables, home monitoring tools such as glucose or blood pressure monitors and mobile applications to monitor specific conditions (Kawu et al, 2023). Accuracy may vary depending on the type of technology used as well as correct technique and ability of the patient to record

results. PGHD provides a rich, continuous dataset that can enhance personalized care, but also introduces challenges in data standardization and integration with clinical records (Khatiwada et al, 2024).

Digital Health Tools (DHTs) generate vast volumes of data, which may either be continuously generated from multiple sources creating a constant stream of information or which can be generated at set time points determined by the patient (Pyper et al, 2023). Without proper validation and standardization, these data streams may produce inconsistencies, leading to potential misinterpretation by healthcare providers. Certain devices may not always provide fully accurate readings, as their performance can be influenced by factors such as the quality of the device, calibration issues, environmental conditions and user's operational ability (Kitt et al, 2020).

AI can be incorporated into DHTs to streamline workflows by filtering generated data and assisting healthcare professionals in reviewing specific readings that require action, such as abnormal result identification from wearable devices (Maddula et al, 2022). This process avoids the need of manually analysing all daily data and focus only on relevant readings which require intervention by the healthcare provider. AI may also be used to assist in identifying a patient's likelihood of developing conditions such as diabetes, hypercholesterolaemia or cardiovascular disease, enabling early intervention or referral. This is done through in-depth analysis of algorithms related to genomic data, lifestyle habits and physiological parameters measured (NE Almansouri et al, 2024; Hassan & Omenogor, 2025). More advanced versions of such technology also provide

educational resource and personalised guidance and motivation, tailored to a particular patient's lifestyle (Cahn et al, 2018; Gray et al, 2022).

Smart Medical Devices and Automation

Improved patient care and treatment may be offered through the innovate design of medical device technology (Nagy, 2021). One example of modern technology includes continuous blood glucose monitors, which make use of a small sensor embedded under the skin to measure glucose levels in the interstitial fluid approximately every five minutes. These sensors, which can remain in place for up to seven days, may be paired with a mobile app as well as insulin pumps (Dey et al, 2025). Patients may access real-time readings and can also be notified when levels indicate a deviation from the normal range. Such integration allows for timely insulin delivery, minimising hyperglycaemic or hypoglycaemic events, maintaining stable glucose control and improving long-term health outcomes (Rhee et al, 2020).

Smart insulin pens are another form of modern technology related to diabetes management, which function like standard insulin pens but have the added capability to record and store data of each insulin injection (Kompala & Neinstein, 2022). This data may be shared with the patient's healthcare provider to monitor adherence to therapy. Newer models also feature bolus dose calculators and reminder alerts to support correct dosing. Smart insulin pens are more expensive than traditional insulin pens, however they are less costly than insulin pumps and are especially beneficial for patients who struggle with calculating doses accurately or patients who fail to adhere to therapeutic care plan (Sy et al, 2022).

Pharmaceutical operations can gain significant advantages from automation tools, which facilitate routine processes, freeing up staff time and workload, allowing for more time to focus patient-centred activities and clinical responsibilities (Zayas-Cabán et al, 2021; Martini 2024). Automated inventory systems allow for tracking and organising stock levels, identify expired products and enabling quick cross-branch stock checks to identify locations or suppliers with available products. Robotic Dispensing Systems further improve efficiency in pharmacies by automating counting, bottling and dispensing, allowing pharmacists to dedicate more time to patient care. However, effective inventory control remains crucial to avoid workflow disruptions from machine errors (Cao et al, 2023).

Emerging Digital Innovations

Beyond conventional digital tools, digital drugs are a new and emerging form of medications embedded with tiny sensors inside them that activate when exposed to stomach fluids (de Miguel Beriain & Morla González, 2020; Wang 2025). These sensors send signals to an external patch on the patient's body, which records health data throughout the day, stores it via a connected device and makes it available for both the patient and their healthcare provider to review (Vallejos et al, 2017).

Andreoni et al (2021) proposed the use of health pods in healthcare settings, such as pharmacies, where patients can quickly monitor various physiological parameters using non-invasive, assisted or self-guided methods. The pods generate instant reports that patients can review with pharmacists to discuss their results and receive necessary guidance. This approach enhances patient autonomy while ensuring professional oversight for interpretation and follow-up care.

Virtual Reality (VR) and Augmented Reality (AR) technologies are being tested for staff training, patient education and clinical simulation (Iqbal et al, 2024; Tene et al, 2024). The integration of VR and AR in pharmaceutical education and patient engagement represents a promising frontier for digital health innovation. These immersive tools enhance learning, reduce training risks and improve patient understanding of complex procedures or medication regimens (Çatak & Kilinç, 2025).

1.9 Rationale, Aims and Objectives

Pharmaceutical sectors in Malta are undergoing a rapid shift toward digitalisation, encompassing electronic health records, e-prescribing, robotic introduction and patient portals. These technologies carry the potential to enhance efficiency, reduce errors, improve transparency and create more sustainable workflows. Alongside these benefits, threats such as cybersecurity threats, challenges with data integrity, workforce readiness, interoperability gaps and regulatory compliance burdens are prevalent. In a small market, finite resources, any miscalculations, fragmented investments, poor integration or inadequate training may result in setbacks. Although international guidance on digitalisation exists readily online, it is often not applicable in Malta's framework and fails to support the day-to-day challenges faced by pharmacists, prescribers, regulatory officers and workers in the PI. This situation creates a need for locally grounded, evidence-based guidelines that supports adoption while reducing risk.

The aims were:

- To assess the risks and opportunities of pharma digitalisation ecosystems.
- To develop guidelines for stakeholders to mitigate risks of pharma digitalisation.

The objectives were to assess risks and opportunities surrounding digitalisation across pharmaceutical ecosystems and to develop actionable, stakeholder-informed guidelines for risk reduction. To address this gap, the study was designed around three interconnected phases.

Phase 1: Carried out semi-structured interviews across five pharmaceutical sectors using a SWOT analysis framework.
Phase 2: set up a focus group to prioritise these threats on a 5x5 risk matrix, based on impact and probability of occurrence.
Phase 3: Findings were consolidated into a draft guideline, structured around practical themes, then refined through expert validation.

By combining stakeholder perspectives with structured risk assessment and expert review, the project aimed to deliver a framework that is not only theoretically sound but also adaptable and practical for those directly involved in shaping Malta's digital pharmaceutical landscape.

Chapter 2 Methodology

The purpose of this chapter is to outline the methodology employed in this study and to evaluate the approach used to achieve its aims and objectives.

2.1 Study Design Overview

The research is divided into three main phases. Phase 1 focused on a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis, carried out through semi-structured interviews with physicians, pharmacists in patient care settings, quality assurance officers, regulatory affairs officers and medicine procurement officers. Participants were selected to ensure representation from diverse pharmaceutical sectors, enabling a comprehensive understanding of digitalisation challenges and opportunities. An application for ethics approval was sought and obtained from the Faculty Research Ethics Committee (MED-2023-00346) (Appendix I). Phase 2 involved a focus group discussion with selected stakeholders to quantify and prioritise risks identified in Phase 1. Risks were evaluated using a 5x5 risk matrix where the probability of an event occurring and the severity of its consequence was considered, identifying risks requiring targeted interventions. Phase 3 focused on the development of evidence-based guidelines to address the prioritised risks and support the effective implementation of pharma digitalisation. These guidelines were validated by an expert panel consisting of one stakeholder from each field studied in phase 1. The panel included one physician, one community pharmacist, one clinical pharmacist, one quality assurance officer from the Pharmaceutical Industry (PI) and one regulatory affairs officer. Guidelines were then refined for potential adoption and integration in practice. The study was designed in a way where one phase informed the next to ensure a logical progression from identifying risks to actionable recommendations (Figure 2.1).

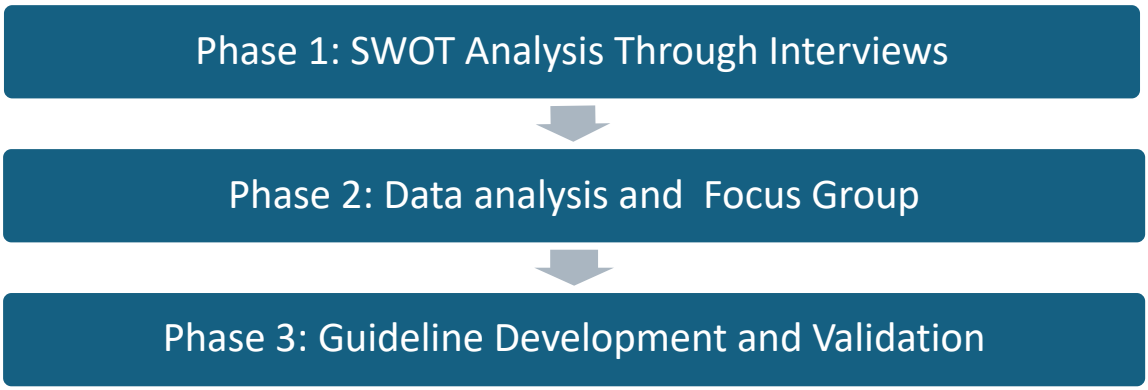

Figure 2.1: Methodology Overview

2.2 Phase 1: Strengths Weaknesses, Opportunities and Threats Analysis

Relevant literature served as basis for the development of interview questions, which exploited the use of open-ended question design to encourage participants to elaborate on their perspectives, providing qualitative data focused on the strengths, weaknesses, opportunities and threats of pharma digitalisation (Hammar et al, 2016; Baratta et al,2021; Kulkov, 2021; Vonbach et al, 2023). Interview questions were structured into five main sections: Section A: Demographic data, Section B: Understanding the extent of digitalisation in the participant's company/institution and Sections C through F: identifying the strengths, weaknesses, opportunities and threats of pharma digitalisation (Appendix IIa). This structure ensured a consistent framework between interviews while still allowing for the flexibility of stakeholders to express relevant insights on their respective sector.

An information letter giving a brief overview of the study, as well as a consent form were developed to be disseminated prior to each interview to establish trust with participants whilst also ensuring they were fully aware of the study's purpose before taking part. Validation was carried out by a panel of seven members: one clinical pharmacist, two community pharmacists, two pharmacists working in the PI, one PI manager and one lay person. The inclusion of a lay person was made to assess the clarity of interview questions.

Interviews with physicians, community pharmacists, quality assurance officers from pharmaceutical companies, regulatory affairs officers and clinical pharmacists, were undertaken. A total of thirty interviews were carried out, involving 6 stakeholders from each sector, where interviews were held once with each individual. Participants were chosen by convenience sampling recruited by the principal researcher while ensuring a proper age and gender distribution to avoid bias. Convenience sampling was employed in this study due to the specialised expertise required from different personnel in various pharmaceutical sectors. Members from the validation panel were not allowed to participate, therefore avoiding potential conflict of interest or undue influence on the data collection process. Interviews were conducted in a semi-structured format, lasting approximately 40 minutes, either in person or via online platforms depending on participant preference.

Data was analysed by pooling all qualitative responses, systematically sorting them into thematic categories and an overview of sector-specific strengths, weaknesses, opportunities and threats for pharma digitalisation were identified. Responses from

similar concepts were merged and results where then arranged into the final SWOT framework. Frequency counts were calculated to determine the "n" value for each theme and included in the SWOT representation. Confidentiality was maintained through transcripts anonymity and all data was stored securely under lock and key accessible only to the research team.

2.3 Phase 2: Focus Group Set-up

A focus group was setup comprising of five different stakeholders: one physician, one community pharmacist, one quality assurance officer from the PI, one regulatory affairs officer and one clinical pharmacist to ensure a balanced representation of different pharmaceutical sectors from phase 1. Interview participants or validation panel members were not eligible for participation to avoid influence and maintain independence between data collection from the two different phases. Each member was handed a booklet consisting of compiled list of identified threats from phase 1, along with instructions for the scoring process and reference criteria to be used (Appendix IIb). The identified risks from interviews were prioritised according to a risk score given by a focus group, translating qualitative data to quantitative presentation. The focus group bridged the qualitative data from phase 1 with quantitative prioritisation through structured risk ranking on a matrix model.

A score on a Likert score between 1 and 5 (1 denoting the lowest score) was given for probability of an event occurring and the severity of consequences where criteria for quantification were pre-determined by the researcher to ensure consistent

scoring between all participants (Dumbravă et al, 2013). Probability and severity scores were illustrated on a 5x5 risk matrix (Figure 2.2) and the product of the two scores, the Risk Priority Number (RPN), was used to categorise and prioritise risks (Duijm, 2015).

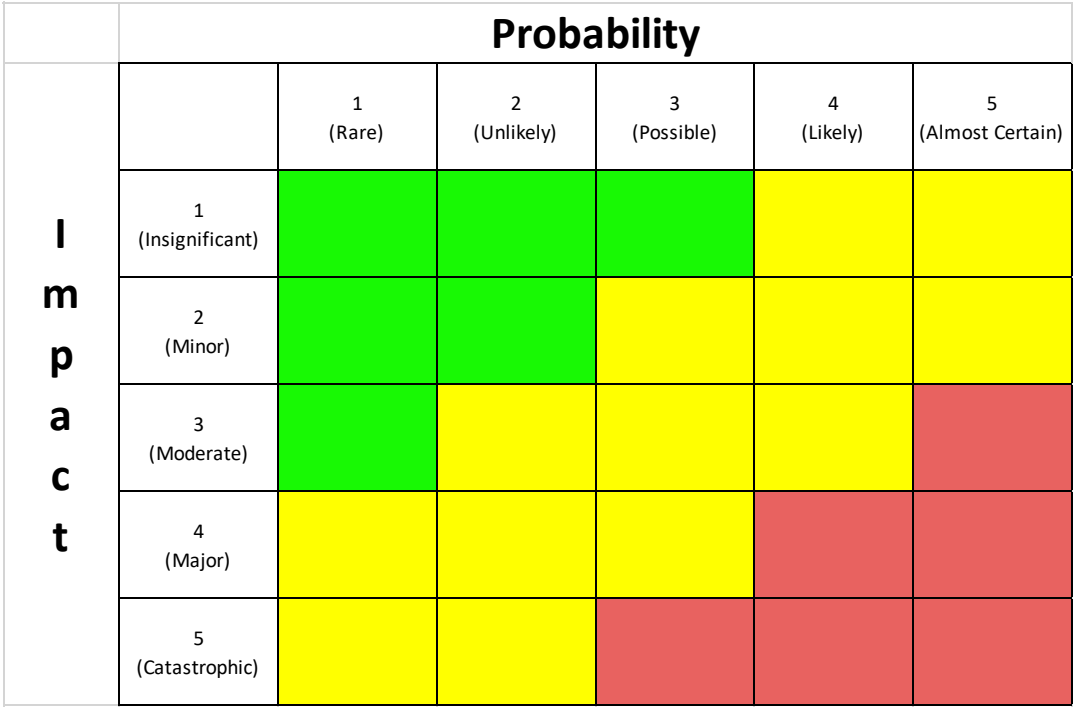

Figure 2.2: 5x5 Risk Matrix. Adapted from: Duijm NJ. Recommendations on the use and design of risk matrices. Safety Science. 2015;76:21-31. doi:10.1016/j.ssci.2015.02.014.

Probability and impact criteria were validated by the members of the focus group at the start of the session. Risk categories and 5x5 matrix models were also validated by the same panel. For each risk, an RPN score was calculated for each individual stakeholder, then an average RPN was calculated. Focus group results are compared and presented as average RPN scores. Probability and impact criteria are presented in Table 2.1 and Table 2.2 respectively.

Table 2.1: Probability Criteria. Adapted from: Dumbravă V, Iacob VS. Using probability–impact matrix in analysis and risk assessment projects. Journal of Knowledge Management, Economics and Information Technology. 2013;42:76-96.

Score	Classification	Description
1	Highly Unlikely	Event is highly unlikely to happen under current circumstances.
2	Uncommon	Event is possible but unlikely to happen in the foreseeable future.
3	Could Happen	Event is neither likely nor unlikely, may happen under the right circumstances.
4	Expected to Happen	Event is likely to occur at some point in the future.
5	Highly Likely	Event is almost certain to happen in the future based on current trends, practices or systems.

Table 2.2: Risk Criteria. Adapted from: Dumbravă V, Iacob VS. Using probability–impact matrix in analysis and risk assessment projects. Journal of Knowledge Management, Economics and Information Technology. 2013;42:76-96.

Score	Classification	Description
1	Insignificant	Risk presents minimal disruption, with little to no noticeable effect that is easily managed. No significant intervention required.
2	Minor	Risk causes minor setbacks or delays that are inconvenient but manageable. Issues may be addressed with minimal effort.
3	Moderate	Noticeable risk, causing disruptions or challenges, requiring active management. Such issues may have broader consequences if not addressed properly.
4	Major	Risks lead to serious disruptions and require significant effort. May lead to longer-term consequences.
5	Catastrophic	Risk results in major and potentially irreversible consequences. Require extensive recovery efforts and could jeopardize the organization's viability.

An RPN value 1-4, signifies a low risk level, defined by a green colour. An RPN value between 4-12 denotes a medium risk level and is defined by a yellow colour. An RPN value between 15-25 signifies a high-risk level and is defined by a red colour (Table 2.3).

Table 2.3: Risk Categorisation

RPN Score	Colour Code	Level of Risk
1-4	Green	Low
4-12	Yellow	Medium
15-25	Red	High

An RPN value of 4, having the impact and probability scores of 1x4 or 4x1 was categorised as a low risk, whereas an RPN value of 4 having been obtained by impact and probability score of 2x2 was categorised as medium risk. This distinction was made to avoid underestimating or overestimating risks when relying solely on the RPN value. This also ensures that both probability and impact scores were adequately accounted for.

Risks with the highest RPN scores were discussed with the focus groups and risk mitigation strategies were put forward when a score of 3+ was given for probability and/or impact. This ensured that scenarios more likely of causing operational disruption were given attention and preventive measures could be planned to minimise potentially harmful or disruptive events.

2.4 Phase 3: Guideline Development

Interview results, as well as the focus group discussion, were used to develop guidelines aimed at providing sector-specific recommendations to minimise risks associated with digital introduction across various pharmaceutical sectors. Risk mitigation strategies suggested by stakeholders during the focus group were taken into consideration, creating evidence-based recommendations in the form of structured guidelines (Appendix IV).

The guideline framework was organised into two main phases: an assessment and planning section and thematic implementation guidelines. Guidelines were validated by a panel of experts which include one stakeholder from each respective field in this study: one physician, one community pharmacist, one quality assurance officer from the PI, one regulatory affairs officer and one clinical pharmacist.

Section 1: Assessment and Planning

The first section of the guidelines, focusing on assessment and planning, was developed by integrating insights from the SWOT analysis and the focus group discussion. Interview findings highlighted variation in digital readiness across pharmaceutical sectors, with some organisations equipped with basic systems while others faced gaps in infrastructure, IT support or workforce competence. These differences were captured in the SWOT analysis, which identified both strengths, such as existing e-prescribing and weaknesses such as limited training or resources.

The focus group further prioritised risks related to inadequate preparation and utilisation of resources, highlighting the need for structured evaluation before larger scale implementations. A stepwise framework was therefore designed, serving as a readiness assessment which included gap identification, objective identification and prioritisation of investments. Documentation and stakeholder engagement were also embedded to ensure accountability and to create measurable reference points. This helps stakeholders make decisions with regards to which investment has the highest potential or impact and move to a pilot project.

Section 2: Core Implementation Guidelines

The second part of the guidelines was developed around thematic domains that were identified as recurrent concerns by stakeholder engagement during the SWOT analysis. The selection of specific themes was further validated through the average RPN scores during the focus group, which ranked these areas among the highest priorities based on probability and impact.

Strengths and opportunities identified during interviews were used as basis for recommendations on mitigating the identified risks. This study combined risk mitigation strategies, mostly supported by the focus group with insights gathered from earlier interview data. The guideline development process not only prioritised risks by severity and likelihood but also incorporated solutions proposed directly by stakeholders themselves. This process ensured that the final thematic guidelines were evidence-based and adaptable to different pharmaceutical settings while remaining aligned with systematically derived risk priorities.

2.5 Dissemination of Findings

An abstract was accepted for poster presentation at the 83rd FIP World Congress of Pharmacy and Pharmaceutical Sciences, Copenhagen, Denmark, 31 August – 3 September 2025.

(See List of Publications and Abstracts)

Chapter 3 Results

This chapter details the results obtained during phase 1 to 3 of the study.

3.1 Phase 1: Interviews Through SWOT Analysis

A total of 30 interviews were carried out with 30 stakeholders between January 2024 and August 2024. Interviews were divided into 6 main sections: Section A through F. Data collected was inputted into Excel, for result pooling and identification of trends. From the results obtained, a Strengths, Weakness, Opportunities and Threats (SWOT) chart was developed and common themes among different areas of pharma were identified (Figure 3.1).

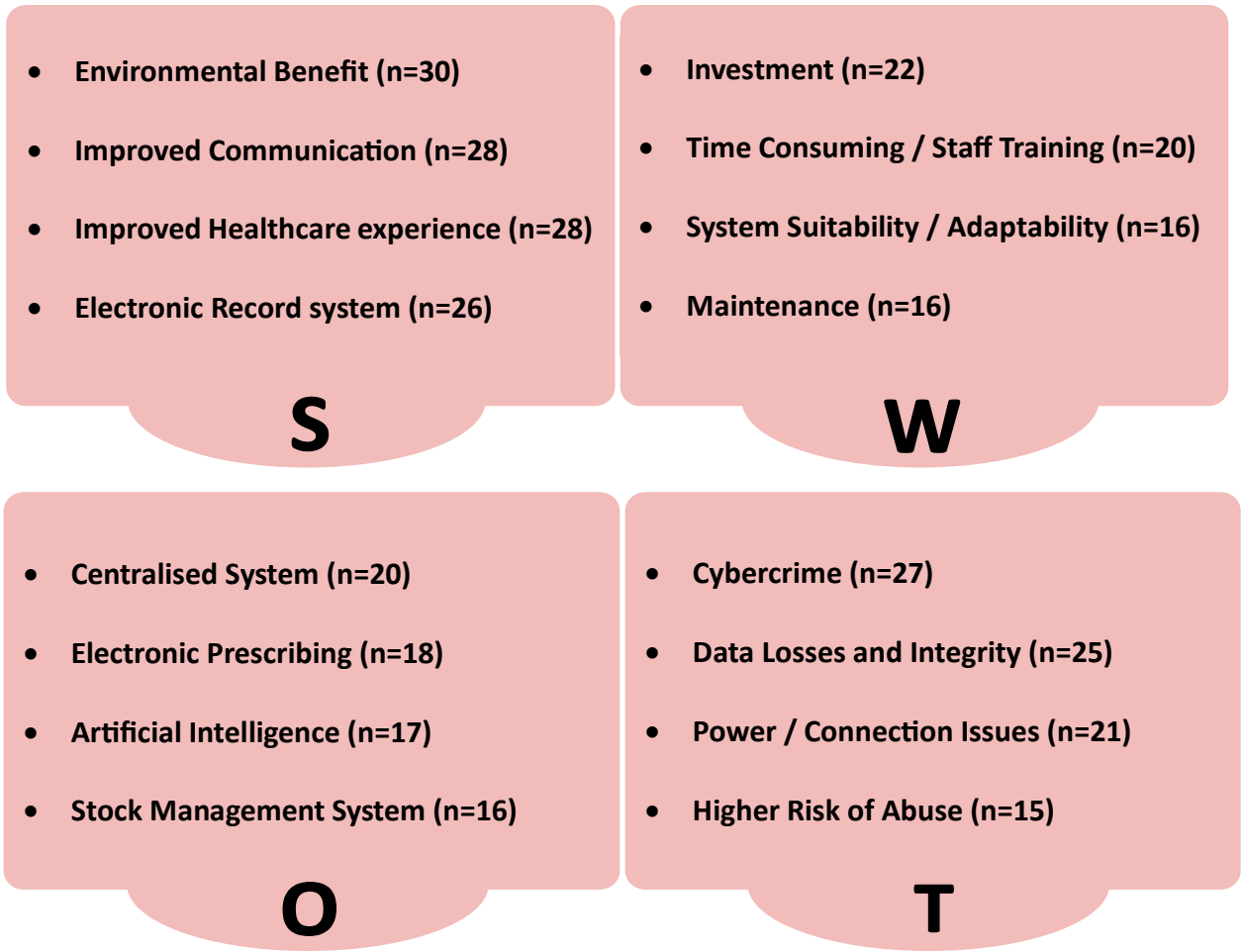

Figure 3.1: SWOT Analysis Overview (n=30)

Sections A and B: Demographics and Current Usage of Digitalisation

A total of 12 female and 18 male participants were chosen, 28 of which have a Malta Qualifications Framework level of 7 or higher. Participants were asked regarding years of practice in their respective sector. A total of 6 participants had 5 or less years of experience, 8 participants had 6 to 10 years of experience, 7 participants had 11 to 15 years of experience, 4 participants had 16 to 20 years of experience and 5 participants had over 20 years of experience.

Current usage of digitalisation varies across different pharmaceutical sectors, however different ways of communication are the most common form of digital adoption in the pharmaceutical sector. Digital communication tools are most widely adopted as a form of engagement between different pharmacies, patients, stakeholders, healthcare providers and suppliers within the industry. The most predominant method of digital communication were emails, reported by 20 stakeholders, followed by phone calls or simple messaging systems by 14 participants. A total of 7 participants also use social media platforms as a method of communication between individuals. These results highlight the sector's reliance on accessible channels for exchanging information, following up patient cases and scheduling appointments. Different tools vary in formality, however all come with an ability to reach different audiences at a cost-effective price and easy implementation in day-to-day situations.

Patient based digital systems are also used such as online patient dashboards (n=8), online appointment systems (n=7) and patient data or sharing portals (n=7). Implementation of such tools enable healthcare providers to review treatment

information and improve the overall healthcare experience through a more informed approach to each specific case. The pace of adoption for such systems may be influenced by regulatory challenges such as General Data Protection Regulation (GDPR) where patient data is involved as well as infrastructure limitations for systems available and user digital literacy or accepting change.

Five participants reported the use of an online ordering system, facilitating logistics and administrative efficiency where processes are streamlined through an online system. Different operational priorities, cost and complexity of implementing such systems reflect the relatively low usage across different sectors. Digital inventory systems are widely used in the Pharmaceutical Industry (PI), where 5 out of 6 participants from the PI adopt such a system. A further 4 out of 6 community pharmacies utilise such online stock record systems. Finally specific digital systems are offered by different institutions, including telehealth related services such as telemedicine or helplines (n=4) and virtual consultations (n=2). Online portals are also used for guideline or information dissemination (n=1).

Section C: Strengths

A total of 30 participants agreed that the major strength of pharma digitalisation is related to the environmental benefit, highlighting reduced paper usage and greener operational workflows. Twenty-eight participants argue that the employment of digitalisation in pharma improves the patient's healthcare experience and facilitates methods of communication and retention of information, particularly through enhanced digital health services. A total of 26 participants utilised an electronic

record system in their respective sectors, whilst 2 participants plan on its introduction in the future.

Twenty-five participants expressed a positive perception of Artificial Intelligence (AI) and digital technologies, with emphasis on their potential in supporting decision making, detecting drug interactions and personalised patient care. Increased efficiency and reduced workload through automation was reported by 22 participants, related to reduction of repetitive tasks and faster information retrieval.

The implementation of cloud-based systems allowing for remote connectivity was noted by 18 participants, enabling secure data access from multiple locations and improving interdepartmental collaboration. Sixteen participants believe that digitalisation offers improved safety through backups, easier traceability and reduced human errors, improving documentation management control and accuracy. The use of digital trend monitoring and statistical tools was seen as a strength by 13 stakeholders, whilst 9 participants identified improved pharmacovigilance and safety reporting as processes facilitated by digitalisation.

Additional strengths mentioned include improved collaboration with external healthcare providers (n=7), the ability to integrate systems and bridge the gap between the public and the private sector (n=5) and the facilitation of patient education through digital means (n=5). Participants also identified a competitive edge when adopting innovative technologies at an earlier stage than competitors (n=4) which positions an organisation at the forefront of the evolving pharmaceutical sector.

Section D: Weaknesses

A total of 22 stakeholders regarded that the financial investment required for implementing digital systems as a major weakness of pharma digitalisation which includes a high upfront cost for software and hardware, as well as maintenance and running fees. Low support for full robotisation was also evident, with 20 participants giving it an average acceptance risk of 2.2 out of 5. Twenty participants highlighted the time-consuming nature of the transition process, particularly in relation to staff training and manual inputting, noting that lengthy onboarding operations may delay realisation of benefits. This goes hand in hand with the lack of trained personnel or Information Technology (IT) capability, resulting in a skill gap as pointed by 18 stakeholders, indirectly increasing reliance on external consultants or support services.

System suitability and adaptability were also noted as concerns, with a total of 16 participants reporting challenges in aligning digital solutions with the specific needs and infrastructure of their respective settings. Sixteen stakeholders argue regarding periodic maintenance required to ensure the system runs smoothly. A further 13 participants highlighted fragmented or incomplete digital systems, making them unusable in healthcare settings. Twelve participants pointed to recurring issues such as system errors, bugs, interface issues and difficulty with upkeep, leading to operational disruptions and decreased user confidence. Nine stakeholders warned regarding over-dependence on technology which may result in the loss of manual oversight or control, raising potential risks if systems fail or produce inaccurate outputs without sufficient human verification.

Additional weaknesses mentioned during the interviews include the poor user friendliness of a system (n=8), resistance from end-users or staff to adopt a new system (n=8) and increased vulnerability to cyberattacks or data breaches (n=7). Five participants argued regarding the challenges related to integrating a digital system across different platforms or departments due to compatibility issues.

Section E: Opportunities

Twenty participants recognised the potential benefits of implementing a centralised healthcare system with a unified interface across different pharmaceutical sectors, enhancing digital collaboration. Eighteen participants regarded electronic prescribing as another key opportunity for digital transformation in pharma, emphasising its role in improving patient safety by reducing prescription and medication errors whilst improving efficiency and dispensing traceability. The integration of advanced technologies such as AI and machine learning in pharmaceutical systems was considered as an opportunity by 17 participants, optimising treatment selection and enhancing efficiency across the supply chain.

Sixteen stakeholders highlight the use of digital stock management systems as an opportunity for digital advancement. A total of 15 participants suggested room for advancement in post-market surveillance through structured reporting frameworks, digital risk scoring tools and trend prediction analytics, strengthening pharmacovigilance and regulatory compliance. Telehealth expansion and improved patient outreach were reported by 14 participants, whilst noting the growing potential of digital platforms to support health communication and engagement

strategies. Thirteen participants argue that a digital ordering or stock-keeping system is another opportunity for digitalisation in pharma, facilitating inventory control. Ten participants identify the use of digitalisation towards improved research and development by utilising broader data for library screening and molecular studies. Increased promotion and education via digital content was identified as an opportunity by 9 participants particularly in raising public awareness about disease prevention or medication information.

Additional opportunities mentioned include the expansion of patient dashboards and digital health records to improve patient care using interoperable systems (n=7) and enhanced traceability of medicinal products from manufacturing to dispensing via blockchain or advanced tracking technologies (n=6). Other stakeholders highlighted the potential of predictive analytics for supply forecasting (n=5) and the role of digitalisation in improving clinical trial recruitment and monitoring (n=4).

Section F: Threats

Cybersecurity risks were identified as the most prominent threat, with 27 participants expressing concern over the potential for cybercrime within digital pharmaceutical systems, including hacking and phishing attempts targeting sensitive data. Data-related issues were also prevalent, as 25 participants argued regarding risks associated with data losses and comprised data integrity. Twenty-one participants acknowledged that power outages and internet connectivity problems pose a threat to the reliability and continuity of digitalisation in pharma. Fifteen stakeholders argue that digitalisation increases the risk of abuse and misuse of data and information. Regulatory and legal issues such as unclear or outdated

legislations, policy gaps and GDPR compliance were identified as a threat towards digital advancement in pharma by 14 participants.

The rapid pace of digital transformation or the resistance to change was identified as a threat by 13 participants, indicating barriers towards implementation. Job insecurity or pay reduction was a concern for 12 stakeholders due to automation replacing human workforce. Ten participants identified system abuse as a threat of digitalisation which may include unauthorised data access, misuse or tampering. The absence of clear digital leadership and corrective or preventive action structures was highlighted as a threat by 8 participants, limiting the ability to respond to failures effectively.

Additional threats mentioned include the dependency on third party vendors or proprietary systems which may limit flexibility or force certain platform usage (n=7) and lack of interoperability between systems resulting in fragmented data, therefore reducing efficiency (n=6). Some participants also warned regarding the potential for incorrect patient data entry or misidentification leading to clinical errors (n=6), ethical challenges around patient consent and data ownership (n=4).

The overall findings highlight the potential benefits as well as the potential negative aspect of digital introduction in pharma. Addressing these concerns will be critical to ensure a sustainable and effective introduction in each sector. Identified threats were discussed in a focus group during Phase 2 of the study.

3.2 Phase 2: Focus Group Analysis

A focus group was set up with 5 different stakeholders: 1 community pharmacist, 1 clinical pharmacist, 1 physician, 1 regulatory officer and 1 manager in the PI. This composition ensured a balanced representation of different pharmaceutical sectors involved in Phase 1 of the study. A total of 15 threats were prioritised according to an average Risk Prioritisation Number (RPN) and risk mitigation strategies were put forward (Appendix III). The aim of this phase was to transition from qualitative identification of risks during the SWOT analysis to a structured quantitative prioritisation that supports evidence-based decision making.

3.2.1 Threats of Pharma Digitalisation

The threat with the highest average RPN score, was related to cybersecurity risk, with a score of 13.8. All 5 participants agreed that digital transformation is inherently dependent on robust IT security infrastructure, emphasising the need for a higher investment going towards protective measures such as antivirus software, firewalls, encryption protocols and other preventive software. In addition to hardware and software safeguards, 4 stakeholders recommended regular staff training to improve awareness of cyberthreats and enable employees to detect malware, phishing attempts or unauthorised system access at an early stage. Three stakeholders highlighted the importance of routine secure password changes to further strengthen access control, while two emphasised the role of physical security measures such as restricted server rooms or sensitive device storage to authorised personnel only as an additional protective layer.

Regulatory and validation challenges resulted as the second highest threat with an average RPN score of 11.6. A total of 3 stakeholders agreed that certain pharmaceutical laws, digital health regulations and validation frameworks are outdated and require revision or updating before large scale digital systems can be legally implemented. This includes alignment with evolving international standards Three participants further recommended the incorporation of both internal and external auditing, to ensure ongoing compliance and traceability. Two stakeholders proposed that companies directly employ or contract personnel from the legal or regulatory area within the company. This allows for timely guidance and professional advice when modifying or introducing new systems. One participant suggested engagement with relevant health authorities, while another highlighted the value of user validation whereby staff assess the systems, confirming functionality and compliance before full deployment.

Time and training requirements ranked third for highest RPN average score with a value of 11.4. All 5 participants acknowledged the steep learning curve involved with the transition to a digital system, particularly in the pharmaceutical sector due to strict regulatory guidelines. Three stakeholders suggested outsourcing training to specialised providers or third party individuals to reduce the burden on internal teams, complemented by periodic refresher sessions to maintain familiarisity and compliance with the digital system. Three stakeholders argued that it is also important to maximise resources and ensure proper time management, especially during the initiation process. Two stakeholders suggested that having a user-friendly interface, further assists employees for better system handling and understanding, significantly reducing training times.

Risk of abuse or misuse was given an average RPN score of 9.6, with stakeholders emphasising the need for strict access controls, secure device use, periodic password updating and periodic training. Other challenges included resistance to change (RPN 9.4), power or connection issues (RPN 9.4) and loss of operational control (RPN 8.8), each requiring tailored risk mitigation strategies ranging from phased system introduction to infrastructure upgrades. Lower-scoring risks, include system suitability and adaptability (RPN 8.4), data confidentiality (RPN 8.0), workforce concerns (RPN 7.8), financial burden (RPN 7.2) and reduced patient interaction (RPN 6.4). The risk with the lowest RPN average score is related to human intervention, indicating that despite technological advances and automation, an element of human profesional oversight will always be required in the pharmaceutical sector.

3.3 Phase 3: Guideline Development

Guidelines were derived from interview and focus group evaluation, for application across different pharmaceutical sectors (Appendix IV). Their purpose is to provide a structured, evidence-based framework that facilitates the introduction of digitalisation across different pharmaceutical sectors. Guidelines also ensure that the implementation processes are aligned with regulatory requirements as well as maintaining professionalism and patient safety.

Section 1: Assessment and Planning

The assessment and planning section of the guidelines was developed to serve as the foundation, to help in understanding the organisation's current position in terms

of digitalisation. Stakeholders participating in the SWOT analysis and focus group stressed the importance of planning before large-scale introductions, therefore the section highlights the importance of conducting a structured assessment of current operations, to fully understand the current situation. Threats categorised as high- and medium-priority during the focus group may be mitigated via structured implementation strategies and clear objectives, as indicated by this section of the guidelines. Inadequate preparation may result in under-utilisation of resources, workflow disruptions or financial burdens in the future. From these results, the first section of the guidelines was structured as a step-by-step process adopting the style of a standard operating procedure. The first section is divided into five key steps to understand the needs and capacity of the organisation, before introducing any form of digitalisation.

Step 1 in the guidelines stresses the importance of assessing digital readiness before any major implementation. This evaluation encompasses existing infrastructure, hardware and software inventories, security protocols, staff competencies and availability of IT support. Its impact is to provide organisations with a clear picture of their starting point, ensuring that future digital initiatives are built on a realistic understanding of capacity. Establishing this foundation allows for better decision-making in the planning or implementation process.

Step 2 highlights the value of understanding inefficiencies or unmet needs that digitalisation could address. By linking digital initiatives to identified gaps in operations, the guidelines help ensure that investments are targeted and purposeful. This prevents resources from being directed toward technology for its own sake,

instead aligning projects with stakeholder-identified priorities. The impact is a more efficient, evidence-driven introduction of digital tools.

Step 3 involves listing clear objectives specific to the organisation in which digitalisation will occur. This step ensures that under any environment, initiatives remain relevant, focused and consistent with professional standards and patient-centred outcomes. Its value lies in fostering alignment between digital adoption and the unique responsibilities of each sector, avoiding generic approaches that risk overlooking local priorities.

Step 4 is aimed at prioritising digital projects determining which should be implemented first. By focusing on high-impact, lower-complexity initiatives, organisations can build momentum while managing risk. Pilot testing is recommended to gauge system feasibility and user acceptance before wider deployment. The practical effect of this step is to reduce costly failures, promote stakeholder confidence and allow early refinements that strengthen larger scale implementation.

Step 5 emphasises on the importance of feedback from stakeholders and users to identify gaps or opportunities with the newly implemented system. The importance of clear communication and regular checkpoints assesses progress and identifies emerging challenges immediately to allow for timely adjustments where necessary. Briefing sessions or training are recommended to maintain familiarity with the new system.

Collectively the ‘Assessment and Planning` section of the guidelines serves as a preparatory framework. Subsequent thematic implementation guidelines may then be applied in context that has been critically analysed. The inclusion of this section in the guidelines emphasises the importance of clear understanding, planning and alignment between needs and chosen digital solutions.

Section 2: Core Implementation Guidelines

The second part of the guidelines is a representation of results from the 30 interviews and focus group with stakeholders. These results were divided into 7 main themes, each representing a specific area of pharma digitalisation that were identified as essential during data collection. Recommended actions are suggested within each theme, drawn directly from stakeholder feedback and risk mitigation strategies put forward during the focus group. The purpose of this section is to provide an actionable guide for introducing digitalisation which aligns with the previous planning framework.

Cybersecurity and Data Integrity

Cybersecurity emerged as the highest-priority concern in the focus group (RPN average of 13.8) and the guidelines address this risk directly. This section provides risk mitigation plans for strengthening data security, ensuring system resilience and protecting sensitive patient information. These include employing robust IT infrastructure with proper firewall, antivirus and malware protection, as well as making use of access control and incorporating two-factor authentication and role-based permissions. The use of timestamping, version control and secure backups further preserve data integrity and facilitate traceability. Staff training must not only

focus on system usage, but specific training related to cybersecurity and regulatory obligations such as GDPR must be in place.

The impact of these measures builds trust in digital systems while also safeguarding organisations from the reputational and financial consequences of data breaches. For interconnected healthcare entities in Malta, coordinated security standards and rehearsed response procedures are essential to maintaining system stability and safeguarding patient data.

Workforce and Training

Workforce and training theme was also evident in the SWOT analysis with 20 participants identifying it as a weakness whilst also having an average RPN of 11.4 during the focus group. The lack of digital competence and insufficient training were identified as barriers to adopting digital systems.

Guidelines highlighted the value of utilising a user-friendly system to increase acceptance as well as periodic training and refresher programmes. This is important in maintaining system familiarity especially following updates or changes.

Regulatory Compliance and Validation

The pharmaceutical sector operates under strict regulatory frameworks, highlighted in the SWOT analysis as well as the focus group with and RPN of 11.6. This section identifies mitigation strategies addressing these risks such as inadequate validation procedures and non-compliance and recommends early involvement of legal or regulatory experts during system selection and implantation to ensure alignment

with both local and European standards including good manufacturing practice and GDPR.

These guidelines suggest the integration of compliance features embedded in the new system which involves audit trails, automated reports and role-based access to provide accountability. Regular internal validation and ongoing monitoring of regulatory updates must also be in place to ensure regulatory compliance and prevention from becoming outdated.

Infrastructure and Technical Reliability

Focus group results highlighted that technical failures such as power outages or connectivity issues may have operational impacts. Mitigation strategies to address these challenges are included in this theme which includes installing a fail-safe system such as generators, battery backups, dual internet service providers and selecting providers with proven reliability and scalability. The guidelines also suggest that the new system must also include offline or mobile functionality. Preventive maintenance protocols such as scheduled hardware checks, regular updates and replacements must also be integrated in the implementation process.

System Suitability, Integration and Adaptability

Issues of system incompatibility for the pharmaceutical sector, poor integration and limited adaptability may give rise to fragmented digital projects. The guidelines recommend piloting systems before expanding to a larger scale. Adjustments to meet local requirements and alignments are necessary to ensure generic systems do not give rise to compliance issues. During interviews, 16 stakeholders

recommended the promotion of an interoperable system between hospital, community and clinical setting, which is also included in the guidelines aimed at improving data flow across different pharmaceutical sectors.

Financial Planning and Investment Strategy

Twenty-two stakeholders agree that financial challenges are a threat to digitalisation during interviews. Focus group participants highlighted the importance of phased investment and strategic resource allocation which are included as mitigation strategies in these guidelines. This theme also includes securing funding from sources such as the European Union, private partnerships or institutions to distribute financial burden. To evaluate return on investment, stakeholders must look at efficiency gains, error reduction, staff satisfaction and compliance improvements.

Human Factors and Professional Roles

In pharmaceutical setting, the human role and patient interaction is an important aspect. Risks of digitalisation include loss of professional control, loss of patient interaction, workforce anxiety and unemployment. This section of the guidelines includes mitigation strategies including support systems to the traditional professional roles and suggests oversight mechanisms such as peer reviewing and quality assurance. These guidelines suggest that job role changes should also be discussed with employees as part of adaptability process of digital introduction. The preservation of patient engagement is important to ensure digitalisation enhances the healthcare experience in pharmaceutical practice.

These guidelines will guide stakeholders during digital implementation processes in the pharmaceutical space by providing them with risk mitigation strategies for the identified threats. The guidelines are designed in a framework applicable to different pharmaceutical sectors which provide evidence-based strategies to mitigate identified threats of digital introduction. This aims at increasing the likelihood of successful digital adoption. These serve as basis to enhance patient healthcare experience and optimise the benefits of digital transformation across all pharmaceutical sectors.

Chapter 4 Discussion

4.1 Digitalised Technology in Pharmacy

This study set out to examine the opportunities and risks associated with digitalisation across Malta's pharmaceutical ecosystem and to develop evidence-based guidelines that support its safe and effective implementation. Using a three-phase methodology, the research combined stakeholder perspectives with structured risk prioritisation, producing a set of practical guidelines relevant to professionals, policymakers and organisations across different sectors.

In Phase 1, semi-structured interviews revealed both optimism and caution. Strengths such as efficiency gains, improved communication and sustainability benefits were acknowledged, but concerns around financial pressures, workforce readiness and technological adaptability were also evident. These insights informed Phase 2, where a focus group was setup to prioritise identified threats on 5x5 risk matrices based on impact and probability of occurrence. Cybersecurity emerged as the most pressing concern, followed by regulatory challenges and workforce training demands, highlighting that digitalisation risks extend beyond technology to governance, policy and human factors.

Phase 3 consolidated findings into thematic guidelines covering seven domains, including cybersecurity, workforce development, regulation, infrastructure resilience, interoperability, financial planning and preservation of patient interaction. By grounding recommendations in stakeholder experience and proportionate to Malta's scale, the study bridges international best practice with local feasibility, offering a context-sensitive framework for digital transformation.

Results also demonstrate that digitalisation is not viewed solely as a technological upgrade but as an organisational and cultural shift. Stakeholders repeatedly stressed the need for training requirement, ongoing support and workforce engagement as central to the success of digital initiatives. This recognition shifts the conversation from procurement of technology to broader change management, where staff readiness and acceptance are as critical as the technical systems themselves.

Findings of this study aided in the development of guidelines to facilitate the digital transformation of Malta's pharmaceutical sector. The research has successfully identified sector-specific opportunities and risks, prioritised them through a systematic process and translated them into actionable guidelines that balance ambition with feasibility. This study demonstrates that small health systems can adopt digitalisation through approaches that are grounded in evidence, informed by stakeholder input and suited to local resources. The study combines academic insights with practical solutions, strengthening understanding and supporting better policies for digital introduction in the pharmaceutical sector.

The outcomes of this study align with existing literature that has explored the growing role of digitalisation in the pharmaceutical sector. The research findings reinforce several widely reported opportunities of digital transformation, including improved efficiency, sustainability and patient-centred care, but they also present consistent concerns in the literature regarding cybersecurity, regulatory clarity, workforce readiness and financial barriers. These results prove that Malta's experience in digital implementation mirrors global trends, yet is also shaped by the unique scale, resources and structure of its pharmaceutical sector.

The identification of key strengths of digitalisation was a central outcome of this study with results showing enhanced communication, process optimisation and environmental sustainability, particularly noted by stakeholders across community, hospital and industrial pharmacy. These findings are strongly supported by existing research, which highlights how digital transformation can streamline workflows, reduce redundancies and promote greener practices by minimising reliance on paper (Hambleton & Aloizos, 2019; Reis et al, 2019). The shift towards more efficient and transparent communication channels also aligns with observations from Gong et al (2021), who describe digitalisation as a strategic re-mapping of organisational workflows, enhancing collaboration across stakeholders. This correspondence indicates that the benefits perceived locally are consistent with those recognised internationally, suggesting that even smaller health systems are set to gain from the global momentum of digital integration.

Cybersecurity was prioritised by the focus group as the biggest threat, receiving the highest risk prioritisation score. This emphasis correlates closely with literature, which identifies cybercrime, hacking and data breaches as major barriers to digital adoption in healthcare systems worldwide (Joy et al, 2024; Triplett et al, 2024). Results from this study recommend the use of robust Information Technology (IT) infrastructure, including encryption, firewalls, multi-factor authentication and regular training, echoes global calls for enhanced cyber hygiene and proactive risk management in healthcare digitalisation. Results prove that stakeholders ranked cybersecurity as the highest risk, reinforcing the global recognition that without trust in data protection, the benefits of digital health cannot be fully realised.

Another outcome with strong alignment to published literature is the recognition of workforce readiness and training as critical determinants of successful digitalisation (Yan et al, 2025). Stakeholders reported that lack of digital literacy, insufficient training and the time burden of onboarding new systems act as barriers. This corresponds with international research noting that digital health interventions often fail when end-users lack the necessary skills or support to engage with them effectively (Cornejo Müller et al, 2020; Mahajan et al, 2020). The importance of structured education and professional development is similarly highlighted by Çatak & Kilinç (2025), who emphasise the need for training programs to embed digital tools into routine clinical decision-making. This finding highlights that digital transformation is not only shaped by technology itself but also by the skills and readiness of the people using it.

Regulatory and validation challenges were identified as significant threats during phase 2. Stakeholders highlighted how outdated frameworks and unclear policies often hinder the implementation of digital technologies within pharmaceutical areas. The recommendations emerging from this study, such as early engagement of regulatory professionals, systematic auditing and improved communication with authorities, mirror published calls for updating and aligning regulatory standards to support a smoother digital transition.

Financial burden was another weakness identified, particularly in relation to the high upfront costs of hardware, software and staff training (Graham, 2024). Small- and medium-sized organisations were seen especially vulnerable to this pressure, with stakeholders warning that expenses could discourage innovation or delay the

adoption of new systems (Faridi et al, 2020). Similar barriers are consistently reported in the literature, where digitalisation is often described as a costly process requiring strategic investment to ensure long-term sustainability (Choy et al, 2024). Odekunle et al (2017) also noted that in lower-resource settings, financial strain often compounds with limited infrastructure, slowing digital adoption further. This study's recommendation for careful resource allocation and the use of external funding or grants reflects similar approaches proposed in previous research, to prevent the indirect transfer of costs to patients (Lanham et al, 2016).

Infrastructure challenges were also discussed by participants, with concerns raised about the reliability of internet connections and continuity of power supply (Iyanna et al, 2022). Although Malta is relatively advanced in terms of infrastructure, stakeholders still identified potential vulnerabilities that could disrupt critical processes. The literature similarly stresses that the success of digitalisation is closely tied to stable infrastructure, with unreliable power or internet acting as a major barrier in other health systems (Mensah, 2023a; Mensah, 2023b). In Ghana, for example, Khan et al (2025) report that poor connectivity and unstable electricity limited the adoption of electronic pharmacy initiatives. While Malta faces different conditions, the alignment with these studies highlights the universal importance of planning for redundancy, including backup power systems, reliable internet provision and offline functionality where necessary.

Concerns regarding the impact of digitalisation on professional roles and patient interaction also mirrored trends described in previous studies. Several stakeholders expressed fear that increased automation might reduce patient contact or diminish

pharmacists' role in clinical decision making. This apprehension aligns with findings by Zhang (2022), who reported that the clinical role of pharmacists has so far only been marginally influenced by technological innovation. At the same time, Piercy and Gist-Mackey (2021) suggest that automation should not be viewed as replacing the workforce but as a way of removing repetitive tasks, thereby allowing professionals to focus on patient-centred responsibilities. The inclusion of guideline recommendations to safeguard patient engagement and preserve human oversight reflects this balance, ensuring that technological change complements rather than replaces the pharmacist's role.

The opportunities identified in this study also align with international literature. Stakeholders viewed Artificial Intelligence (AI), centralised health records, telehealth expansion and advanced pharmacovigilance as promising areas of development. These themes are similarly observed in published research which highlights how AI, predictive analytics, cloud-based systems and blockchain technologies can support personalised medicine, improve data security and enhance collaboration across healthcare systems (Elragal & Haddara, 2012; Omar et al, 2021; Tolley et al, 2023). Results from this study therefore reflects the global recognition that digitalisation has the potential not only to improve operational efficiency but also to reshape healthcare delivery into a more connected and patient-centred model.

Findings from this study align with existing research on digitalisation in pharmacy and healthcare. Opportunities such as improved efficiency, enhanced communication and innovative technologies were recognised in both stakeholder

perspectives and published literature. Similarly, risks related to regulatory barriers, workforce readiness, financial costs, infrastructure and loss of patient interaction were repeatedly highlighted in both contexts. By focusing on Malta, this study contributes locally grounded evidence to the global discussion on digitalisation, proving that while opportunities and risks are shared internationally, their impact is shaped by the realities of each healthcare system.

The findings of this study carry important implications for both local and international contexts, as they translate stakeholder perspectives into a practical and validated set of guidelines for the digitalisation of Malta's pharmaceutical sector. The impact of this work lies not only in identifying risks and opportunities but also in providing a structured framework that is directly applicable to practice. By capturing opinions from pharmacists, regulatory officers, industry representatives, physicians and clinical professionals, the study ensures that its outcomes are grounded in healthcare experience rather than abstract theory. This participatory approach enhances the relevance of the findings for stakeholders who will ultimately implement digitalisation.

The study offers actionable recommendations that can support a smoother transition towards pharma digitalisation within Malta's healthcare system. As a small country, Malta faces unique challenges in terms of resources, infrastructure and workforce distribution, yet these very characteristics also allow for greater coordination and rapid implementation of change. The guidelines proposed are tailored to this balance, recommending proportionate measures that ensure feasibility while still addressing critical areas such as cybersecurity, workforce training, regulatory

alignment, infrastructure resilience and patient-centred practice. Their relevance is therefore immediate, providing stakeholders and policymakers with an achievable and evidence-based framework to facilitate their implementation process.

The relevance of the study also relates to daily professional practice. Pharmacists and other healthcare professionals will benefit from clear guidance on how to integrate digital tools without compromising patient safety or professional roles. The emphasis placed by stakeholders on maintaining human oversight and preserving patient interaction is particularly impactful, as it reassures professionals that digitalisation is designed to support, rather than replace, their clinical judgement. This aligns with wider evidence that successful adoption of digital health technologies depends on workforce acceptance and engagement and the guidelines contribute directly to fostering that acceptance.

Another area of impact relates to education and training. This study highlights that workforce readiness is a major determinant of success, supporting published recommendations that digital health education should be embedded in pharmacy curricula as well as in continuous professional training. By recommending ongoing training and setting appropriate timeframes for staff to adapt to new systems, the findings provide a guidance framework in designing relevant educational content. This not only prepares the current workforce but also ensures that future generations of pharmacists are equipped with the digital skills necessary to thrive in a modern healthcare environment.

The relevance of the findings also extends internationally. While the study is situated in Malta, many of the themes identified: cybersecurity, financial pressures, regulatory clarity and infrastructure resilience, are widely recognised in other healthcare systems. By demonstrating how these challenges can be mitigated in Malta, the research contributes a case study that enriches the global literature. Smaller health systems often face similar constraints and the Maltese experience offers insights into how proportionate and context-sensitive solutions can be designed. This makes the guidelines relevant not only locally but also for comparable countries seeking to adopt digital health strategies without the resources of larger organisations.

The impact and relevance of this study are both practical and academical. Practically, it provides a clear, evidence-based guideline that can guide Malta's pharmaceutical sector through the opportunities and risks of digitalisation. Academically, it contributes to the international dialogue by demonstrating how small health systems can develop locally grounded, yet globally relevant approaches to digital transformation. The study therefore ensures that the enthusiasm for digitalisation is matched with structured safeguards, proportionate strategies and a firm commitment to patient-centred care.

4.2 Limitations

The main limitation of this study is the relatively small and sector-specific sample size. Although thirty stakeholders from five pharmaceutical sectors were interviewed, the reliance on convenience sampling whilst being practical, may have

introduced potential selection bias. Participants were recruited through professional networks, which may have limited the diversity of opinions gathered. Expanding the pool of participants, particularly through random or stratified sampling, could have ensured greater representativeness across age groups, years of practice and organisational size, thereby strengthening the generalisability of the findings. Participants may have been more willing to engage because of pre-existing interest or experience in digitalisation, potentially skewing results towards more digitally aware perspectives.

Another limitation relates to the focus group design. The focus group was intentionally kept small to ensure manageable, in-depth discussion across sectors, however this also limits the generalisability of quantitative outputs such as Risk Prioritisation Numbers (RPN)s. Different participant compositions might have generated slightly different prioritisation of risks. Similarly, the RPN method, while structured and widely used, still relies on subjective probability and impact ratings, which may not capture the full complexity of risk assessment. The small number of participants may not have fully captured the complexity of sector-specific risks. For example, multiple stakeholders from the pharmaceutical industry or regulatory affairs might have highlighted different perspectives on financial and legal challenges.

Another limitation relates to the absence of direct patient involvement during the study which also carries certain drawbacks. While the study emphasised workforce and patient engagement issues, the data remains largely from professional

stakeholders. Including patients directly could have provided additional insight into acceptance, usability and equity considerations.

The study also faces limitations in scope and time. Interviews were conducted over several months, but rapid technological evolution means that specific systems, threats or opportunities may shift quickly, potentially outdating certain observations. Finally, although the guidelines were validated by experts, they have not yet been piloted in real-world settings. Their true utility and feasibility will only become clear through implementation and feedback.

The study was confined to the Maltese pharmaceutical context, which, while relevant for local policymaking, limits broader transferability. Given that infrastructure, regulatory frameworks and workforce readiness vary significantly across countries, repeating similar studies in other contexts would allow for international comparison and adaptation of the guidelines.

4.3 Recommendations for Future Research

This study can be further developed based on the limitations and findings. The first step involves piloting the proposed guidelines in real-world pharmaceutical settings such as community pharmacies, hospital pharmacies or pharmaceutical industry sites. By applying the framework in practice, its feasibility, usability and impact on day-to-day workflows can be assessed. After a defined trial period, follow-up evaluations with stakeholders could help determine whether the guidelines effectively support digital integration, improve efficiency and mitigate risks. These

evaluations may include surveys, interviews or focus groups to compare perceptions and outcomes before and after implementation. Guidelines may then be disseminated to different stakeholders to facilitate the process of digital introduction in their respective sector. Future work should also examine the ethical and legal implications of emerging technologies, such as AI, blockchain and digital drugs, to ensure guideline updates remain relevant as innovations progress.

Another important avenue for future work involves extending the study to a wider sample of participants including patients and the public. Their perspectives on trust, usability, access and engagement are critical to ensure digitalisation supports equitable, patient-centred care rather than widening digital divides. While this research engaged thirty stakeholders across five sectors, larger-scale investigations could strengthen the evidence base and provide more robust data on sector-specific needs. Future studies could also explore perspectives from policymakers and IT professionals, who also play a role in digital adoption but were not directly included in this research. Their involvement would broaden the scope and ensure that the guidelines reflect a multi-stakeholder approach.

Cross-country comparisons also represent a valuable next step. Malta's small size and healthcare system present unique opportunities and challenges that may not apply elsewhere. Repeating the study in other European or international contexts would allow for benchmarking and adaptation of the guidelines to different regulatory, infrastructural and cultural settings. Such comparative studies could identify best practices and accelerate global harmonisation in pharmaceutical digitalisation.

Financial burden was consistently highlighted as a threat to digital introduction. Quantitative analyses of cost–benefit and return on investment should complement qualitative findings. The development and research on evidence-based economic modelling can help stakeholders justify and sequence investments.

Another possible direction is integrating the findings into pharmacy education and professional development. The results of this study highlight the importance of workforce readiness, training and user-friendly systems in ensuring successful digital implementation. Embedding digital health competencies into undergraduate pharmacy curricula, as well as providing ongoing training opportunities for practicing pharmacists, could prepare for a more digitally driven future.

Future studies may also focus tracking the way digitalisation evolves over time, measuring not only adoption rates but also outcomes in patient safety, efficiency, staff satisfaction and regulatory compliance. This would provide much-needed evidence on the long-term impacts of digitalisation across pharmaceutical ecosystems.

Finally, the framework could be expanded beyond pharmacy to other healthcare professions. The same way pharmacists face challenges in digital adoption, so do physicians, nurses and other healthcare providers. By adapting the guidelines to these groups, the study could contribute to a more cohesive, interoperable digital healthcare ecosystem. This expansion would ensure that digitalisation efforts are aligned across the healthcare system, thereby maximising benefits for both professionals and patients.

4.4 Conclusion

The aim was to assess the risks and opportunities associated with pharmaceutical digitalisation in Malta and to construct a framework that enables its safe and effective implementation. This study was driven by the rapid global expansion of digital technologies, together with the need to balance innovation with safety, efficiency and regulatory compliance. A strengths, weaknesses, opportunities and threats analysis conducted via semi-structured interviews, followed by a focus group, generated a comprehensive overview of stakeholder perspectives and outlined strategies for effective digital integration during this study.

Results confirmed that digitalisation is widely regarded as a key driver for future advancement across different pharmaceutical sectors. Community and clinical pharmacists valued its potential for improving patient communication, greater convenience through electronic prescribing and improved inventory management. Pharmaceutical industry representatives emphasised the role of automation and robotics in improving efficiency and reducing human errors, while regulatory officers recognised the advantages of digital platforms in streamlining data archiving and communication. These perspectives demonstrated a positive outlook towards digitalisation, with stakeholders recognising its potential to enhance healthcare accessibility, streamline operations and strengthen system efficiency.

This study also identified important challenges that must be addressed to realise the full benefits of pharma digitalisation. High implementation costs, ongoing training requirements and data security concerns were pointed out as major barriers. Cybercrime was highlighted as a critical risk, reflecting the vulnerability of digital

health systems. Additionally, the complexity of regulatory validation processes within the pharmaceutical sector was seen as a hindrance to timely adoption. The prioritisation of these risks emphasised the need for targeted interventions, including investment in IT infrastructure as a prevention against cybercrime, improved professional training and harmonised regulatory frameworks.

This research highlights the importance of collaboration among pharmacists, industry workers, regulatory authorities and policymakers to ensure that digitalisation is implemented responsibly and sustainably. The framework developed through this study potentially provides a strategic foundation for governing digitalisation responsibly. By balancing risks with opportunities, it ensures that digital tools are not adopted for their novelty alone, but are harnessed to enhance safety, efficiency and equity in pharmaceutical care. This framework transforms abstract concerns about cybersecurity, regulation and workforce preparedness into actionable pathways for sustainable implementation, providing policymakers, regulators and practitioners with a clear guide for managing digitalisation in a structured and proportionate way. Digitalisation holds the power to reshape the entire pharmaceutical infrastructure, however its success depends on the proactive anticipation and management of risks, continuous investment in people and infrastructure and, above all a shared commitment to safeguarding patient wellbeing as the guiding principle of innovation.

This study demonstrated that with a clear, evidence-based framework, Malta and other small health systems, can potentially achieve a model of digital transformation that is both ambitious and innovative yet safe and accountable.

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List of Publications and Abstracts

Abstract accepted for poster presentation at the 83rd FIP World Congress of Pharmacy and Pharmaceutical Sciences, Copenhagen, Denmark, 31 August – 3 September 2025.

Risks and Opportunities of Digitalisation in Pharmaceutical Ecosystems: A SWOT Analysis Approach

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Introduction: The pharmaceutical industry is undergoing rapid digital transformation, integrating artificial intelligence (AI), robotisationand electronic prescribing systems to enhance efficiency, reduce errorsand improve patient care. The COVID-19 pandemic accelerated this transition, highlighting the benefits of remote patient monitoring, automatation processes and digital health. Digital introduction possesses challenges such as cybersecurity threats, financial pressure and issues related to system suitability and acceptance. Current research primarily focuses on the benefits of digitalisation, with limited exploration of mitigation strategies for its risks. The study aimed to identify risks and opportunities of digitalisation in different pharmaceutical ecosystems.

Method: A strengths, weaknesses, opportunitiesand threats (SWOT) analysis was conducted through interviews with 30 stakeholders from different sectors: community pharmacy, hospital pharmacy, pharmaceutical industry, pharmaceutical regulatory sciencesand medical practice. Interview responses were analysed and risks identified were presented to a focus group comprising of five stakeholders, one from each field involved in the SWOT analysis. Each stakeholder rated 15

identified threats on a 5×5 risk matrix based on probability and severity, where scores ranging from 1 to 5 were given. Risk Priority Numbers (RPNs) were calculated to rank and prioritise risksand mitigation strategies were then put forward.

Results: Key strengths identified included improved communication, enhanced efficiency, error reduction and environmental benefits through digital systems. Community pharmacists highlighted the advantages of e-prescribing and patient communication platforms. Clinical pharmacists and physicians emphasized the potential of AI in diagnostics and treatment optimisation. Regulatory officers and pharmaceutical industry personnel recognized digitalisation as a driver for streamlined workflows and enhanced data traceability. Challenges that were identified include cybersecurity threats, investment costs and loss of patient interaction. Staff training burdens, data losses and system failures due to connectivity or power disruptions were also identified as major threats. Legal and ethical concerns regarding patient privacy and security were highlighted. Opportunities included AI-driven softwares for different pharmaceutical sectors and automated dispensing. The integration of a centralised healthcare system with a common interface for electronic prescriptions and interprofessional communication were also mentioned. Participants agreed that, if strategically implemented, digitalisation could significantly improve patient outcomes and workplace efficiency.

Conclusion: Digitalisation presents strengths and challenges in pharmaceutical ecosystems. While enhancing efficiency and accuracy, issues such as cybersecurity risks, high costs and workforce adaptation require interventions.

Topic Area: Social and Administrative Pharmacy

L-Università ta' Malta | Faculty of Medicine & Surgery | Department of Pharmacy

Risks and opportunities of digitalisation in pharmaceutical ecosystems: A SWOT analysis approach

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INTRODUCTION

The pharmaceutical sector is undergoing rapid digital transformation, integrating artificial intelligence (AI), robotisation, and electronic prescribing systems to enhance efficiency, reduce errors, and improve patient care. The process of digitalisation poses challenges, including cybersecurity as a concern. Digitalisation presents opportunities in the pharmaceutical sector, offering efficiency and cost-effectiveness in areas such as community pharmacies and manufacturing.[1]

AIM

To identify risks and opportunities of pharma digitalisation ecosystems.

METHOD

Phase I

A SWOT analysis through interviews with 30 stakeholders; physicians, pharmacists in patient care settings, quality assurance officers from pharmaceutical companies, regulatory affairs officers and medicine procurement officers was undertaken.

Phase II

A focus group comprising of 5 stakeholders, one from each field, was set-up to quantify risks on a 5x5 risk matrix, considering the probability of event occurrence and severity of consequences. A Likert scale from 1 to 5 was used to calculate a risk prioritisation number (RPN) which is the product of Probability and Severity.

RESULTS

Thirty stakeholders; 6 physicians, 6 pharmacists in patient care settings, 6 quality assurance officers from pharmaceutical companies, 6 regulatory affairs officers and 6 medicine procurement officers participated in a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis through interviews. Figure 1 represents the key strengths, weaknesses, opportunities and threats as identified through interviews with 30 different stakeholders. A total of 15 weaknesses and threats were chosen to be quantified during a focus group.

S	W	O	T
• Environmental Benefit (n=30)	• Investment (n=22)	• Artificial Intelligence (n=17)	• Cybercrime (n=27)
• Communication and Information (n=28)	• Time consuming / staff training (n=20)	• E-prescriptions (n=16)	• Data Losses and Integrity (n=25)
• Increased Patient Benefit (n=28)	• System suitability and Adaptability (n=16)	• Centralised system (n=16)	• Power and Connection issues (n=21)
• Improved Workflow and Efficiency (n=22)	• Maintenance (n=16)	• Stock Management system (n=14)	• Higher risk of abuse (n=15)

Figure 1: Key findings from the strengths, weaknesses, opportunities and threats analysis.

Following the focus group, the threat with the highest average RPN score (13.8) was related to cybersecurity, followed by regulatory challenges (11.6). (Figure 2)

The threat with the lowest average RPN score is related to the need for human intervention, having an average score of 6.0

For the 3 threats with the highest RPN, risk mitigation strategies were proposed. Five stakeholders suggested a higher investment towards upgrading IT hardware and software to mitigate cybersecurity risks.

Threat	RPN value
Cybersecurity	13.8
Regulatory Challenges	11.6
Time and Training	11.4
Maintenance	10.8
Risk of Abuse	9.6
Power and Connection	9.4

Figure 2: Major threats of pharma digitalisation

CONCLUSION

Digitalisation presents both strengths and challenges in the pharma. While enhancing efficiency and accuracy, issues such as cybersecurity risks, high costs and workforce adaptation require interventions. Future research should focus on further solutions or risk mitigation strategies.

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Appendices

Appendix I: Ethics Approval

L-Università ta' Malta

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9 January 2024

Mr Gianluca Muscat
Birzebbugia
Malta

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Pharma Digitalisation: Risks and Opportunities

The Faculty Research Ethics Committee is granting ethical approval for the above-mentioned application.

Professor Anthony Serracino Inglott
Chair
Faculty Research Ethics Committee

Appendix IIa: Interview Questions

Part A: Participant Demographics

1. Participant Title
2. What is your highest academic level?
3. Pharmaceutical sector to which participant's institution belongs to:
    - Community Pharmacy
    - Clinical setting
    - Pharmaceutical industry
    - Regulatory
    - Other:
4. Years of experience within the pharmaceutical sector:
    - 5 years or less
    - 6-10 years
    - 11-15 years
    - 16-20 years
    - Over 20 years

Part B: Understanding the current usage of digitalisation within the institution / company

5. How does your company currently engage with customers, stakeholders and healthcare providers in the digital space?

6. Does your institution utilise any electronic record system?
    - Yes -> How is digitalisation currently involved within your institution/company?
    - No -> do you plan on introducing any form of digitalisation?

Part C: SWOT analysis – Strengths

7. How does your institution utilise digitalisation towards their advantage and in what way has this been beneficial?
8. Has digitalisation provided benefits from a marketing perspective?
    - If yes -> In what ways?
9. How do you see the role of artificial intelligence (AI), machine learning (ML) and other advanced technologies in the digitalization of the pharmaceutical industry? Does your institution use any automated tools / robots / machinery?
    - If yes -> has this introduction been beneficial and in which areas do you see the most potential for growth? Do you plan on further introductions?
    - If no -> Do you plan on introducing such systems to your company/institution? Why?
10. How has your company been able to leverage digitalisation to improve patient outcomes and healthcare delivery?
11. On a rating of 1-5 where 1 = strongly disagree and 5 = strongly agree, what do you think of the idea of a complete robotisation / digitalised system in the pharmaceutical field in the future?

12. Which areas do you think have the highest potential for growth in digitalisation employment?

Part D: SWOT analysis – Weaknesses

13. What are the main key challenges your institution has faced upon introduction of automated or digitalised systems?
14. How does your company currently handle and manage the potential ethical issues that may arise from digitalization such as data privacy, security and bias?
15. Do you think the introduction of an automated / electronic systems may be interfere with employment or conditions of work for employees/workers?
    - If yes -> In what ways?
    - If no -> Why not?
16. Do you think digital advancement will have any effects on the relationship/connection between the industrial side of pharma and the patient-based perspective?
    - If yes -> Do you think this would result in a positive or a negative effect on the relationship. How?
    - If no -> Why not?

Part E: SWOT analysis – Opportunities

17. In your opinion do you believe digitalisation will impact the way pharmaceutical products are developed and manufactured? Which would be the top benefits of such innovation? List in order of most affected to least

affected by artificial intelligence introduction to the pharmaceutical industry; R&D, Quality, Sales & Marketing or Storage & Delivery.

18. What kind of data and information do you believe will be most valuable to collect and analyse in the pharmaceutical industry through digital means? Why?
19. What are your institution's opportunities in terms of collaboration and engagement? Is your company employing any steps to develop the necessary skills / expertise in order to take full advantage of pharma digitalisation?
20. How do you perceive a possible transition towards a more digitalised/automated system in your sector? Would you consider introducing such a change if readily available and what opportunities does this provide in your sector?

Part F: SWOT analysis – Threats

21. What threats or risks do you perceive from digitalisation?
22. How do you currently manage these threats, including threats such as security of digital information,
23. What are the main reasons holding back your institution from further development in digitalisation?
24. Do you believe there are any legal or regulatory challenges that must be addressed to fully realize the potential of digitalization in the pharmaceutical industry?

Appendix IIb: Focus Group

Information Sheet and Consent Form Information Sheet for participants in the focus group.

This study, “Developing guidelines for the implementation of digitalised technology in pharmacy”, aims to assess risks and opportunities of pharma digitalisation, as well as to develop guidelines for stakeholders to mitigate risks of pharma digitalisation.

Pharma digitalisation risks were identified from interviews with 30 different stakeholders including; clinical pharmacists, community pharmacists physicians, regulatory pharmacists and workers in the pharmaceutical industry. You will be required to quantify these risks on 5x5 risk matrices. Focus group results will be the basis for guideline development.

Your participation is entirely voluntary. All data collected will be anonymous, treated with confidentiality and solely used for the purpose of this study. Data will be stored in accordance with General Data Protection Regulation (GDPR) and all data will be deleted by end of 2027. The results of this research may be published in a scientific journal, but your identity will be kept confidential.

Instructions for quantifying risks

The 5x5matrix evaluates each risk based on probability and impact. The Risk Priority Number (RPN), the product of probability and impact will be calculated for each risk.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

An RPN value 1-4, signifies a low risk level, defined by a green colour.
An RPN value between 4-12 signifies a medium risk level and is defined by a yellow colour.
An RPN value between 15-25 signifies a high risk level and is defined by a red colour.

You are asked to mark only one box by rating the probability of occurrence of a risk from 1 (highly unlikely) to 5 (highly likely) and the impact of a risk from 1 (negligible negative impact) to 5 (catastrophic).

See the probability and impact criteria overleaf.

When a score of 3+ is given for probability and/or impact, suggest a mitigation in the relevant section.

Probability Criteria

How likely it is that a particular risk will occur.

Rare (1) – Highly Unlikely

- Event is highly unlikely to happen under current circumstances.
- **Probability**: <5% chance of happening.

Unlikely (2) – Uncommon

- Event is possible but unlikely to happen in the foreseeable future.
- Probability: 5-20%.

Possible (3) – Could Happen

- Event is neither likely nor unlikely, may happen under the right circumstances.
- **Probability**: 20-50%.

Likely (4) – Expected to Happen

- Event is likely to occur at some point in the near future.
- **Probability**: 50-80%.

Almost Certain (5) – Highly Likely

- Event is almost certain to happen in the near future based on current trends, practices or systems.
- **Probability**: >80% likelihood.

Impact Criteria for Risks (Negative Consequences)

Insignificant (1) – Negligible Negative Impact

- Risk presents minimal disruption, with little to no noticeable effect that is easily managed. No significant intervention required.

Minor (2) – Slight Negative Impact

- Risk causes minor setbacks or delays that are inconvenient but manageable. Issues may be addressed with minimal effort.

Moderate (3) – Noticeable Negative Impact

- Noticeable risk, causing disruptions or challenges, requiring active management. Such issues may have broader consequences if not addressed properly.

Major (4) – Significant Negative Impact

- Risks lead to serious disruptions and require significant effort. May lead to longer-term consequences.

Catastrophic (5) – Devastating Negative Impact

- Risk results in major and potentially irreversible consequences. Require extensive recovery efforts and could jeopardize the organization's viability.

Validation of Matrix Model

Criteria

Mark only one circle per row

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Probability criteria are clear and comprehensive	O	O	O	O	O
Impact criteria are clear and comprehensive	O	O	O	O	O
Risk categorisations are adequate	O	O	O	O	O
5x5 matrix is adequate	O	O	O	O	O

Comments:

Quantification of Risks through 5x5 Risk Matrices

1. Cybersecurity Risks

Cybersecurity concerns likely due to increasing digital threats and vulnerabilities.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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2. Data Integrity, Lossand Confidentiality

Includes risks related to data loss, leakage, tamperingand misinterpretation of data.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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3. Investment and Financial Burden

Indicates financial challenges and the need for substantial investment in technology or infrastructure.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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4. Time and Training Requirements

Highlights the time and effort needed for training staff and implementing new systems.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

_____

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5. Power and Connection Issues

Refers to instability or loss of power and connectivity that affects operations.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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6. Maintenance and Upkeep

Covers the ongoing need for maintenance and technical support.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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7. System Suitability and Adaptability

Refers to challenges in system appropriateness, integrationand adaptability. Also refers fragmented systems in place.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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8. System Reliability and Understanding

Involves challenges in system comprehension, reliabilityand accountability.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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9. Regulatory and Validation Challenges

Reflects legal / regulatory hurdles, validation needsand compliance requirements.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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10. Risk of Abuse and Misuse

Covers concerns related to potential misuse or abuse of systems or information.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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11. Employment and Workforce Concerns

Addresses potential job reductions due to automation or restructuring. Covers anxiety regarding impacts on pay or career progression.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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12. Loss of Patient Interaction and Relationship

Reflects concerns about reduced human interaction and lowered relationship quality.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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13. Resistance and Acceptability Challenges

Reflects hesitancy or opposition toward adopting new systems and acceptance challenges for new technology.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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14. Need for human intervention

Despite automation, ongoing human intervention is still necessary, posing an operational challenge.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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15. Loss of Control

Covers anxiety about loss of control over processes.

		Probability				
		1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost Certain)
Impact	1 (Insignificant)					
	2 (Minor)					
	3 (Moderate)					
	4 (Major)					
	5 (Catastrophic)					

Strategy (if applicable); _____

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Appendix III: Mitigation Strategies Suggested by Focus Group

Risk	RPN Score	Mitigation Strategy	Number of Stakeholders
Cybersecurity Risks	13.8	Invest in IT infrastructure (firewalls, antivirus, etc.)	5
		Staff training on cyber safety	4
		Regular data backups	3
		Use of secure passwords	3
		Physical security (locked rooms for devices)	2
Regulatory and Validation Challenges	11.6	In-house auditing mechanisms	3
		Hire regulatory personnel or seek legal guidance	2
		Update and review regulations	2
		Communicate with authorities	1
		User-led validation during system use	1
Time and Training Requirements	11.4	Outsourcing training	3
		Resource maximisation	2
		User-friendly system design	2
		Regular refreshers to ensure compliance	2
Maintenance and Upkeep	10.8	On-call or in-house technical support	3
		Training employees on basic maintenance	2
		Ensure system reliability	2
		Preventive maintenance (scheduled checks)	1
		Increase IT department staffing	1
Risk of Abuse and Misuse	9.6	Restrict access rights	4
		Secure devices for workplace use only	2
		Password updates every 3–6 months	2
		Training on abuse prevention	2
		Use of audit trails	1

Resistance and Acceptability Issues	9.4	Implement user-friendly systems	3
		Stage-wise system introduction	3
		Multidisciplinary onboarding approach	2
		Design systems to reduce workload	1
Power and Connection Issues	9.4	Install generators, batteries or backup power grids	4
		Secure reliable system vendors/partners	3
		Implement offline backup systems	2
Loss of Control	8.8	Peer reviewing mechanisms	4
		In-process controls	3
		Prevention checks and human intervention	2
		Upgrade hardware and systems to reduce loopholes	1
System Suitability & Adaptability	8.4	Clear communication & understanding	4
		Tailor systems to Maltese pharma	2
		Scale-up using pilot stages	2
		Develop in-house systems	2
		Conduct proper Research and Development	1
Data Integrity & Confidentiality	8.0	Implement 2FA	3
		Timestamping and audit tracking	2
		Review and trend data access processes	2
		Apply GDPR policies	2
		Assign access by role	1
		Personnel training	1
Employment & Workforce Concerns	7.8	Modify existing roles	4
		Offer re-training opportunities	1

Investment & Financial Burden	7.2	Utilise insider training to reduce costs	2
		Plan steps in advance	2
		Apply for financial grants	1
		Use tendering to avoid monopolies	1
System Reliability & Understanding	6.8	Invest in scalable and 24/7 supported systems	3
		Invest based on evidence and need	3
		Hire reliable developers	2
		Focus on user-friendliness	1
Loss of Patient Interaction	6.4	Emphasise continued patient interaction	3
		Acknowledge that human intervention is essential	2
Need for Human Intervention	6.0	Preventive updates and checks	2
		Acknowledge role of human oversight	1

Appendix IV: Guidelines for Minimising Risks of Pharma Digitalisation Introduction

These guidelines provide a structured framework for the safe and efficient implementation of digitalisation within various pharmaceutical sectors, including;

- Pharmaceutical Manufacturing and Industry
- Hospital Setting
- Community Pharmacies
- Regulatory Sector
- Physicians

These guidelines are based on interviews with stakeholders from each sector, followed by a focus group analysis quantifying threats on a 5x5 matrix model. Its goal is to support decision-making processes and help stakeholders navigate between opportunities and threats of pharma digitalisation, while maintaining compliance, mitigating risks and enhancing professional and patient outcomes.

Assessment and Planning

Prior to introduction of any digital systems or process, each relevant sector must conduct a structured assessment of its current operations. This step ensures digital introduction is relevant and aligns with organisational needs. The process must be adaptable to each setting.

1. Conducting a Digital Readiness Assessment

Each department shall begin by evaluating the current level of digital maturity. This includes;

- Inventory of existing digital infrastructure (hardware, software, connection status)
- Identifying current data management practices (manual or digital workflow systems)
- Identifying staff digital competency level
- Ensuring IT support availability and response capacity
- Identifying and analysing security protocols currently in place

The evaluation should be documented and results will serve as basis for key implementation personnel.

2. Identifying Operational Needs and Gaps

Following the readiness assessment, specific staff members shall identify key areas where digitalisation may offer benefit. Identified gaps or weaknesses must be listed, to serve as guide in choosing the appropriate digital system. The aim is to identify and highlight:

- Inefficiencies in existing manual procedures
- Regulatory or compliance pressures pushing away digital solutions
- Processes lacking standardisation and traceability
- Opportunities for automation

3. Defining Sector-Specific Objectives

Based on the identified needs, each sector within the same organisation must define clear objectives for digitalisation in their relevant area. These objectives must be aligned with professional and patient-centred outcomes and specific to each setting. Objectives shall be realistic and achievable with the organisation's resource limits.

4. Prioritise Implementation Areas

Following objective identification, different areas within the same pharmaceutical sector must be identified based on;

- Potential for risk reduction
- Expected return on investment
- Technical feasibility
- Resource availability

Initially, areas with a high-impact and low-complexity shall be prioritised. Pilot projects shall be launched and if successful, committing to a full-scale implementation.

5. Engage Stakeholders and Building Internal Support

Effective digitalisation requires both technical readiness as well as engagement from users impacted by the new system. The relevant sector shall actively involve different stakeholders from early planning through to execution. Stakeholder engagement shall be structured to include;

- Clear communication
- Opportunities for feedback before or during implementation to address concerns in a timely manner

- Regular checkpoints to assess and review implementation progress as well as evaluate and identify any relevant challenges and adjust as required
- Briefing and training sessions designed to keep end users familiar with the new system

Any activity or review checkpoint must be documented, highlighting any identified gaps and changes made. The implementation process shall remain adaptive to allow for adjustments of tools or strategies according to requirements.

Core Implementation Guidelines

1. Cybersecurity and Data Integrity

Pharmacy sectors must adopt proactive security approaches to mitigate cyber threats and ensure the integrity of digital records and sensitive data within the respective sector.

- Deploy robust IT infrastructure Deploy robust IT infrastructure, including firewalls, antivirus tools and malware protection software, to defend against external threats.
- Enforce strong access controls, utilising features such as two-factor authentication (2FA), regularly updated passwords and role-based access rights.
- Implement data integrity measures, such as timestamping, version control and secure backup systems, supporting easier traceability.
- Conduct regular staff training on cyber security and phishing, GDPR compliance and the proper handling of digital records to prevent breaches from internal mishandling.

2. Workforce and Training

Building Digital Competence and Empowering the Professional Workforce. Training should be viewed as a continuous process rather than a one-time exercise.

- Provide structured onboarding programs or manuals for new digital tools, tailored to different user roles and responsibilities.
- Schedule periodic training and refresher programs to maintain system familiarity and keep pace with updates or changes.

- Prioritise user-friendliness in digital system design to reduce resistance and avoid creating additional workload.

3. Regulatory Compliance and Validation

Digital tools must comply with legal and regulatory requirements. A proactive compliance strategy should be embedded into system design and ongoing operations.

- Engage legal or regulatory experts during system selection and implementation to interpret applicable laws and standards (e.g. GDPR, national medicine regulations).
- Incorporate compliance-by-design principles, embedding audit trails, automated reporting and role-based access within digital platforms.
- Conduct internal validation processes regularly, ensuring that systems meet both technical specifications and legal expectations.
- Stay informed of evolving regulations and update internal processes and software functionalities accordingly.

4. Infrastructure and Technical Reliability

Establishing a reliable infrastructure ensures uninterrupted care, smooth operations and trust in digital systems, minimising potential errors or data losses.

- Install fail-safe systems, including generators, battery backups and dual internet service providers (ISPs), to counteract connectivity and power disruptions.

- Select proven, vendor-supported platforms with a strong track record of reliability, security and scalability.
- Ensure systems include offline or mobile functionality, to allow service continuation even during connectivity outages.
- Implement preventive maintenance protocols, with scheduled checks, updates and hardware upgrades to reduce unplanned downtime

5. System Suitability, Integration and Adaptability

Digital systems must align with the operational realities and requirements.

- Employ pilot digital projects before full-scale deployment, allowing for adjustments based on practical feedback.
- Adjust particular system designs according to local requirements, ensuring compatibility with the Maltese clinical and regulatory framework or workflow.
- Introduce interoperability, enabling data sharing across different pharmaceutical settings such as hospital, community and regulatory areas.

6. Financial Planning and Investment Strategy

Digitalisation requires smart financial planning that balances innovation with sustainability, employing a scalable approach whilst considering resource optimisation.

- Seek diverse funding sources, including EU grants, private partnerships or institutional investment, to reduce the financial burden on one entity.

- Phase investments strategically with the correct planning, starting with high-impact, low-cost implementations and gradually scaling based on results.
- Monitor return on investment (ROI) using metrics such as error reduction, efficiency gains, staff satisfaction and compliance performance.

7. Human Factors and Professional Roles

The human element must be maintained in pharmaceutical ecosystems, since operations may be streamlined, however pharmacy practice remains a human-centred profession.

- Design systems to support, professional judgement, preserving pharmacists' role in patient care and decision-making.
- Include built-in human oversight, such as in-process checks, peer review mechanisms and quality assurance layers.
- Communicate transparently about job role changes, addressing workforce concerns through retraining, professional development and inclusion in planning.
- Prioritise patient interaction, ensuring that digital tools enhance communication not isolate or depersonalise care.