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Knowledge, Attitudes and Perceptions of the Regulation of Medical Artificial intelligence in South Africa: A survey of regulatory professionals

By

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine (Pharmaceutical Affairs)

Johannesburg, March 2025

Declaration

I, Thirosha Chetty declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science in Medicine (Pharmaceutical Affairs) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

A signed plagiarism declaration is included in Appendix A as well as an Ethical clearance certificate from the University of the Witwatersrand Human Research Ethics Committee (H23/11/04) (Appendix B).



_____

(Signature of candidate)

27_____day of_____March_____2025_____in_CAPE TOWN, SOUTH AFRICA_

Ethics Declaration

I, Thirosha Chetty, consciously assure that for the research report: Knowledge, Attitudes and Perceptions of the Regulation of Medical Artificial intelligence: A survey of regulatory professionals, the following is fulfilled:

1) The presented material is an authentic creation of the author, and it has not been disseminated or featured anywhere else

2) The paper is not currently being considered for publication elsewhere.

3) The author of the report has presented their own research and analysis honestly and comprehensively.

An official signed plagiarism declaration has been signed (see Appendix A). Ethical clearance was received from the University of the Witwatersrand Human Research Ethics Committee (HREC, clearance certificate number H23/11/04) (see Appendix B).



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(Signature of candidate)

27____day of___March____2025___in __CAPE TOWN, SOUTH AFRICA_

Dedication

To my family and friends that believed in me – Thank you for your unwavering support and encouragement throughout this journey.

Acknowledgements

My sincere gratitude to my Mom, whose unwavering belief in me and the power of knowledge and wisdom has been a guiding light throughout my academic career. I am thankful to my sister for her continuous encouragement and support. Additionally, I thank my husband for his understanding and patience during early mornings and late nights of research. To my brother and family, colleagues and friends who have authentically supported me throughout this journey. For my family members, who have passed but are never forgotten, your guiding light is always felt. Sincere gratitude to my supervisor Rubina Shaikh for her guidance and to the South African Medical Technology Industry Association (SAMED) for their involvement in this project. Additionally, I am thankful to the participants of my study whose insights and contributions have enriched this study.

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Abstract

Introduction:

The integration of Artificial Intelligence (AI) into healthcare, particularly in medical devices, presents significant opportunities for improving diagnostics, monitoring, and treatment. However, these innovative technologies also pose complex regulatory challenges. In South Africa, regulatory professionals play a pivotal role in overseeing the safe and ethical application of medical AI, yet the regulatory framework remains underdeveloped. This study explores the knowledge, attitudes, and perceptions of South African regulatory professionals regarding medical AI regulation and identifies gaps in existing frameworks.

Aim:

This study aims to evaluate the level of knowledge, understanding, and perceptions of medical AI among regulatory professionals in South Africa. Findings could inform further investigations aimed at developing recommendation strategies to improve regulatory frameworks within South Africa.

Methods:

A quantitative, cross-sectional survey was conducted with 106 regulatory professionals recruited through the South African Medical Technology Industry Association (SAMED) and LinkedIn, yielding a 77.94% response rate. The questionnaire assessed AI knowledge, understanding of AI applications, regulatory challenges, and attitudes toward AI in healthcare. Data were analysed using descriptive and inferential statistical methods, including Kruskal-Wallis ($H = 27.86$, $p < 0.001$), Mann-Whitney U, and Chi-square tests ($\chi^2 = 38.72$, $p < 0.001$). Likert-scale responses measuring attitudes and perceptions were analysed for central tendency (mean: 3.79, median: 4.49) and variability (standard deviation: 0.91–1.14).

Results:

Regarding knowledge, 99.06% of respondents were familiar with artificial intelligence (AI), with 86.8% able to correctly define machine learning (Mann-Whitney $U = 125$, $p < 0.001$). However, only 46.2% were aware of AI applications in healthcare (Mann-Whitney $U = 450$, $p = 0.005$), and an even smaller percentage (23.6%) reported the use of medical AI in their organizations (Mann-Whitney $U = 600$, $p = 0.09$). In terms of regulatory gaps, 81% of respondents felt that South Africa lacked adequate regulatory frameworks for medical AI (Chi-square test: $\chi^2 = 95.79$, $p < 0.001$).

When considering perceived challenges, safety and efficacy emerged as the most critical concerns, identified by 68.9% of respondents, followed by data privacy (63.2%) and algorithm transparency (50.9%). Additionally, 52.8% highlighted the importance of continuous learning in AI systems, and 56.6% emphasized the need for international harmonization of regulations. Attitudes

toward AI were generally positive, as revealed by Likert-scale analysis. There was strong agreement with statements highlighting AI's potential, such as "AI has great potential for use in medical devices for diagnosis, prognosis, and treatment" (mean: 4.49, SD: 0.91). However, scepticism persisted, with 39.6% of respondents neutral on whether AI improves patient outcomes, and the statement "AI will replace physicians in the future" receiving the lowest agreement (mean: 2.12, SD: 1.14). Finally, the demographic profile of respondents showed that the majority were female (72.6%) and highly educated, with 60.4% holding postgraduate qualifications.

Conclusion:

The study highlights a substantial gap between general AI knowledge and practical regulatory understanding among South African professionals. Statistical tests underscored significant differences in knowledge and attitudes. Respondents emphasised the need for robust, localized regulatory frameworks addressing safety, efficacy, data privacy, and ethical concerns. International collaboration with health authorities and harmonized standards were identified as critical for fostering innovation and ensuring the safe integration of AI into the South African regulatory framework.

Implications:

Targeted education, capacity building, and regulatory reforms are recommended to enhance oversight of the integration and implementation of AI in medical devices and diagnostics in South Africa.

List of Abbreviations

AI: Artificial intelligence
ANVISA: Brazilian Health Regulatory Agency
CBER: Center for Biologics Evaluation and Research
CDRH: Center for Devices and Radiological Health
DCCN: Deep convolutional neural network
EU: European Union
FDA: Food and Drug Administration
FTC: Federal Trade Commission (FTC)
GDPR: General Data Protection Regulation
HREC: Health Research Ethics Committee
OCP: Office of Combination Products
MRSA: Medicines and Related Substances Act
NIST: National Institute of Standards and Technology
OECD: Organisation for Economic Co-operation and Development
POPI: Protection of Personal Information
SAMED: South African Medical Technology Industry Association
SaMD: Software as a medical device
SAHPRA: South African Health Products Regulatory Authority
TGA: Therapeutic Goods Administration
TPLC: Total Product Life Cycle
UK: United Kingdom
U.S.: United States
USA: United States of America
WHO: World Health Organization
WITS: University of the Witwatersrand

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CHAPTER 1: INTRODUCTION

This chapter reviews the applications of Medical Artificial intelligence (AI) in the diagnosis and treatment of diseases. It presents a background, problem statement, research question, aim and objectives of the study and concluding with a synopsis of the research report.

1.1 Background

Artificial intelligence and machine learning are driving significant change in the medical device industry. Artificial intelligence commonly known as the 4th industrial revolution, in which machines can simulate human thinking in learning, analysis and in problem-solving (Schwab, 2016). Artificial intelligence was initially introduced in medicine in the early 1970s, to improve medical diagnosis and treatment (Patel, 2009). It was only decades later that AI gained widespread adoption with advancements in machine deep learning (Badnjevic et al., 2021).

Utilisation of artificial intelligence in medicine span basic sciences, translational medicine and healthcare delivery (including administrative work, diagnosis and treatment) (Stern, 2022). AI is described as “ability of a machine to perform cognitive functions that we associate with human minds, such as perceiving, reasoning, learning, interacting with the environment, problem solving, decision-making, and even demonstrating creativity.” (Colins et al., 2021). For the scope of this study, medical AI will be defined as AI and its applications in medical devices and *in vitro* diagnostics.

Many diagnostic and AI treatment applications are defined as a medical device or *in vitro* diagnostic, and are regulated accordingly (Stern, 2022). The World Health Organization (WHO) defines a medical device as: “A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.” (WHO, 2023). Such devices have a key role in the diagnosis and treatment of many diseases, especially within the surgical, radiological, and critical care specialties (Hubner et al., 2021).

The regulation of Artificial intelligence in medical devices presents a unique challenge due to it’s evolving nature. AI systems learn and improve over time, leading to unpredictable behavior that necessitates an adaptive regulatory framework (Liao et al., 2020). Risk stratification is also essential as AI’s risk level varies based on its intended use and complexity (FDA, 2021).

Additionally, AI systems operate as a “black-box”, raising concerns about transparency and interpretability (European Commission, 2020).

The AI risk classification system is used to assess and classify the risks of AI in healthcare. These risks include operational risks e.g. diagnostic errors (Topol, 2019), ethical concerns (e.g. patient data privacy) (Obermeyer & Emanuel, 2016), security risks (e.g. data breaches) (Finlayson et al., 2019) and legal or regulatory risks (compliance and liability) (Jiang et al., 2017b).

1.1.1 Employing AI in Medical Devices and its increasing role in global healthcare

“Artificial intelligence is perhaps the most transformational technology of our time, and healthcare is perhaps AI’s most pressing application” (Satya Nadella, 2019).

AI is enhancing healthcare by improving precision diagnostics, enabling personalized therapy, and optimizing workflows (Ratwani et al., 2024; Fulga et al., 2023). Wearable technology, such as smartwatches, allows for real-time health monitoring, aiding in early disease detection. Given the vast amount of medical data generated, AI is becoming increasingly important in assisting clinicians with diagnosis and treatment decisions (Badnejevic et al., 2020).

Key AI applications in healthcare include:

Precision Diagnostics: AI enhances diagnostic accuracy, often matching or surpassing human experts in radiology, dermatology, pathology and cardiology. Over half of the AI-based medical devices approved between the years 2015 and 2020 were for radiological applications (Bajwa et al., 2021a).

Diabetic Retinopathy Detection: Much work has been done in AI for patient prognosis, for example Google created and trained a deep convolutional neural network (DCCN) using 128,175 retinal fundus images for classification of diabetic retinopathy and macular edema. The advantages have shown improved efficiency, and accuracy (Basu et al., 2020).

Radiotherapy planning: AI- based tools such as InnerEye automate image analysis, and this can improve timelines for cancer diagnosis and treatment planning, It has been further applied to regions such as the head, neck and prostate, streamlining the process of identifying the location of tumors, and determining the dosage of radiation allowing for quicker initiation of life-saving treatments (Johnson et. al, 2024).

1.1.2 Implications of poorly regulated medical devices

The regulation of AI in medical devices is essential for many reasons, each related to the goals of safety, reliability, accountability and ethics. Below are some of the areas in which challenges may be faced with the introduction of AI:

- Patient Safety: Faulty AI systems can misdiagnose patient's conditions, leading to harmful treatments. It is therefore crucial to have regulatory oversight to enhance the safety and reliability of AI systems in healthcare (European Commission, 2020; FDA, 2021).
- Reliability and Accuracy: AI algorithms may introduce biases due to flawed data and improper algorithmic design. (Topol, 2019).
- Ethics: medical AI raises ethical concerns such as data privacy and algorithmic bias. There are challenges of a lack of fairness, transparency and upholding patient rights (Floridi et al., 2018; Mittelstadt, 2019).

1.2 Software as a Medical Device

From the scrutiny of the Medicines and Related Substances Amendment Act (MRSA), software is included in the definition of a medical device in South Africa, however, this regulation does not provide a sufficient AI risk classification as highlighted by Townsend et al., (2023b). Although there are currently no regulations relating to the use of AI in medical devices and diagnostics in South Africa, South Africa stands to benefit from the ethical standards, guidelines, and policies in other jurisdictions.

The European Union has recognized the challenges surrounding liability. To align liability principles, the European Commission proposed the AI Act to encourage responsible deployment of AI critical sectors such as healthcare. Medical devices that fall under the EU's high-risk classification are subject to strict liability, and persons exercising control over the operation/features of the product can be liable for any injuries caused (Jassar et al., 2022). Specific regulation has also been proposed in the US Algorithmic Accountability Act of 2022, and the White Paper titled "A pro-innovation approach to AI regulation, published in March 2023 in the United Kingdom (UK). The European Commission AI Act is the first legal framework worldwide, addressing the risks, ethical principles and safety. The AI Act seeks to shape an environment that fosters respect for human dignity and trust in the interaction of AI technology and human beings, with fostered collaboration and innovation amongst stakeholders. It is part of a wider range of policy measures to support the development of trustworthy AI in Europe and beyond. The AI Act sets a model for AI regulation worldwide, which may encourage South Africa to align AI policies

with international standards, which will facilitate trade and collaboration between regions (European Commission, 2021).

The AI Act sets a strong framework that is relevant in the South African context. The ethical principles outlined in the AI Act resonates with South Africa's pledge to human rights and dignity, as part of its constitution (South African Constitution, 1996). The development of AI guidelines that prioritize ethical principles and human rights can enhance trust in the use of the technology. The AI Act promotes a collaborative approach that can encourage stakeholders (government, academia and industry) in South Africa to work together to create AI solutions that are culturally and contextually relevant (Naidoo, 2021). The importance of data privacy emphasised in the AI Act, parallels with the Protection of Personal Information Act (POPIA) in South Africa and can guide policymakers in shaping the regulations in South Africa to enhance citizens privacy (South African Government, 2013). By taking into consideration the above aspects, South Africa can develop a strong regulatory framework that meets local needs and aligns with international best practices.

1.3 AI in the South African healthcare context

Artificial intelligence certainly has great potential in the South African healthcare sector; therefore, it is crucial to understand the knowledge, attitudes and perceptions of the regulation of medical AI.

The purpose of the study was to gain an understanding of the current knowledge and attitudes of the regulation of medical AI. By understanding the current knowledge and attitudes of medical AI, it can help guide the creation of robust regulatory frameworks that prioritises high ethical principles and patient safety (Reddy et al., 2020). Regulatory professionals have a key role in safeguarding of public health. The perceptions of AI can influence the development of regulatory frameworks, which can then affect patient safety and trust in medical technology (Scherer et al., 2021). The study provides insight relating to the gaps in knowledge among regulatory professionals.

It is important to assess the knowledge, attitudes and perceptions of medical AI amongst regulatory professionals, leading to the fundamental question of how AI in medical devices should be regulated. An essential objective is the advancement of regulatory frameworks to govern AI in healthcare and the need to develop laws and policy that will support "ethical and transparent" use of these technologies (Ameer-Mia et al., 2020). This information could assist in contributing to

foundational knowledge to be adopted in further in-depth investigations, however, these further investigations are most definitely first needed for any development of a recommendatory resource and implementation thereof.

1.4 Problem Statement

Regulating AI in medical devices is a complex activity and necessitates a multidimensional approach. There is a lack of literature on the knowledge, attitudes and perceptions of regulatory professionals of the regulation of medical artificial intelligence in South Africa, and a need for a regulatory framework to foster a safe and efficient use of AI in medical devices (Donnelly S., 2022).

1.5 Aim

The aim of this study is to explore the knowledge, attitudes, and perceptions of regulatory professionals regarding the regulation of medical AI in South Africa.

1.6 Objectives

1) To explore the knowledge associated with the regulation of medical AI with the use of a survey.
2) To explore the attitudes associated with the regulation of medical AI through the use of a survey.
3) To explore the perceptions associated with the regulation of medical AI through the use of a survey.

1.7 Synopsis of the report

Chapter One of this dissertation provides an overview of the research, including the growing role of AI in the medical field and the importance of regulating medical AI. This chapter will outline the objectives, scope and methodology of the study, as well as the significance of the study focusing on why understanding the knowledge, attitudes and perceptions of regulatory professionals is crucial for the successful integration of AI in healthcare.

Chapter Two provides a comprehensive literature review on medical AI in medical devices and the regulation thereof. It outlines current regulatory frameworks and international views on AI, and the challenges and need for AI regulation.

Chapter Three provides a summary of the methodology and study design. Data collection methods and sampling techniques are outlined in this section, as well as how regulatory professionals were identified and recruited for the research. This chapter describes the procedures for data analysis and statistical tests. Ethical considerations, such informed consent and data confidentiality will be addressed.

Chapter Four presents the results of the study by analyzing the knowledge, attitudes and perceptions of the regulation of medical AI in South Africa, in which the data is presented in tables and graphs. Inferential statistics will be used for comparative analysis.

Chapter Five of the dissertation analyses the results of Chapter four as well as the patterns derived from the outcomes of the study. The findings are discussed taking into consideration the existing literature and theoretical frameworks. The implications of the research findings for policy, practice and future research will be examined in this chapter. It may identify gaps in information and suggest proposal`s for enhancing the regulation of medical AI in South Africa.

Chapter Six will provide the key outcomes and conclusions of the study and their implications for the regulation of medical AI. It will offer recommendations for enhancing AI knowledge among regulatory professionals, suggesting strategies for education, development of policies and stakeholder engagement. This chapter will reflect on the limitations of the study and recommend areas for future research.

1.8 Summary

Artificial Intelligence is rapidly advancing in the medical field, enhancing diagnostics, treatment, and patient care. However, its integration poses ethical and regulatory challenges. This study explores the knowledge, attitudes, and perceptions of regulatory professionals regarding the regulation of medical AI in South Africa. Understanding these perspectives may be important for further development of policies and regulatory frameworks and the findings may help bridge knowledge gaps and inform decision-making in the regulation of medical AI in South Africa.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Artificial intelligence is advancing healthcare through its applications in medical devices and diagnostics. This chapter is a literature review that focuses on the regulatory landscape, limitations, and challenges of AI applications in medical devices, taking both the global and South African context into consideration. The chapter further highlights the international regulatory guidance on AI and the implications of the POPI (Protection of Personal Information) Act.

2.2 Limitations and Challenges in the Application of Artificial intelligence

A number of studies have outlined the limitations and challenges presented within the medical Artificial Intelligence regulation context, however, there is no literature supporting this specific to the South African healthcare product's regulatory framework.

Challenges and Limitations:

- Data Quality and Availability: The building block of an efficient AI system is high quality data (Basu et al., 2020). Poor quality data that may be incomplete or biased could result in the AI model's predictions and decisions being flawed. This can result in severe consequences in the healthcare sector (Kietzmann et. Al., 2018). Availability of data may be limited due to patent privacy concerns, thus hindering the development of medical AI technology (Pannu, 2020). The challenge of data collection is patient privacy which leads to limited data availability and therefore limited computational model training.
- Transparency: Due to the complexity of mathematical algorithms, AI systems often function as a black-box (Basu et al., 2020), where the AI program will make decisions and predictions as humans do but cannot communicate its reasons for doing so. Thus, decision-making cannot easily be interpreted by humans (Rudin, 2019). This lack of transparency may make it difficult to trust medical AI systems, where there is a need for understanding the reason behind a diagnosis (Doshi-Velez & Kim, 2017).
- Regulatory and Ethical challenges: There are multiple profound and complex ethical considerations. Data privacy, patient consent and misuse of medical AI give rise to concerns that need to be managed (Floridi et al., 2018). Furthermore, the rapid development of AI surpasses the existing regulatory frameworks, thus making it a challenge for regulators to stay abreast and ensure safe and ethical AI systems (Gasser & Almeida, 2017).

Despite the limitations above, AI is positioned to transform the healthcare industry (Basu et al., 2020).

2.3 Regulatory Landscape and Challenges

With the rapid innovation in technology, various regulatory bodies across the world have developed key regulations and guidelines. Some of these guidelines directly relate to the regulation of AI, to ensure that it is safe, effective and transparent, whilst there are guidelines which are to be further developed to incorporate the use of AI. Table 1 outlines the regulations and guidelines that have been implemented by stringent regulatory authorities across the world.

There are many aspects to consider in regulating AI in medical devices and diagnostics, including data quality, patient confidentiality, traceability and transparency of algorithms (Jiang et al., 2017a). Current regulatory frameworks may struggle to keep pace with the evolving nature of AI systems in medical devices. Regulatory organizations are now looking at new models to assess AI based medical devices, with an emphasis on continuous monitoring and post-market surveillance (Topol, 2019).

Table 1: Regulatory landscape for AI across global regulatory authorities

Country	**Regulatory Body**	**Key Regulations/Guidelines**
USA	Food and Drug Administration (FDA)	Digital Health Innovation Action Plan (2017) - proposed regulatory framework for AI/ML-based medical devices and Guideline on Good Machine Learning Practice (2021)
	Federal Trade Commission (FTC)	Federal Trade Commission Act (15 U.S.C. §§ 41–58, 1914): Consumer protection laws, privacy regulations, and ethical guidelines for AI development and deployment.

Table 2: Regulatory landscape for AI across global regulatory authorities

Country	Regulatory Body	Key Regulations/Guidelines
EU	European Medicines Agency (EMA) European Commission	AI Act (2024) GDPR (General Data Protection Regulation) (GDPR, 2016/679, 2016)
UK	Medicines and Healthcare products Regulatory Agency (MHRA) Information Commissioner's Office (ICO)	Guideline on Good Machine Learning Practice (2021) AI Whitepaper (2023) – Regulatory Approach to AI oversight Data Protection Act 2018, guidelines on AI and data protection.
Canada	Health Canada Innovation, Science and Economic Development Canada	Guideline on Good Machine Learning Practice (2021) Draft Guidance for Machine learning enabled medical devices (2021) Directive on Automated Decision-Making (2019) - emphasizing accountability, transparency, and fairness.
Japan	Ministry of Health, Labour and Welfare (MHLW)	Guidelines for the Review and Approval of Software as a Medical Device (SaMD) (2020)

Table 3: Regulatory landscape for AI across global regulatory authorities		
Country	**Regulatory Body**	**Key Regulations/Guidelines**
Japan (continued)	Cabinet Office, Government of Japan	AI R&D Guidelines for Human-Centric AI, Society 5.0 initiative (2019) and Draft Guidelines – AI in Business (2021)
Australia	Therapeutic Goods Administration (TGA) Office of the Australian Information Commissioner	Regulation of software based medical devices (2021) AI Ethics Framework (2019) And Privacy Act (1988) – Governs AI-related data processing and privacy
Brazil	National Health Surveillance Agency (ANVISA) National Congress of Brazil	Resolution on Good practices for the regulation of Digital Health Products (2022) Legal Framework for AI, Bill PL 21/2020 (2021) – Regulatory foundation for AI governance
South Africa	South African Health Products Regulatory Authority (SAHPRA) Department of Communications and Digital Technologies	Guidelines for the registration of medical devices (2022) Draft AI Policy (2023) – focuses on ethical AI, data protection, and digital transformation. Protection of Personal Information (POPI Act, 2013, enforced 2021)

2.3.1 United States

The United States of America (USA) the Algorithmic Accountability Act is a proposed legislation that aims for companies to assess the effects of automated decision systems and to enforce accountability with the goal of preventing discrimination and bias (US Congress, 2022). In addition, the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) have introduced executive orders and guidelines for the use of AI in specific areas (FTC, 2020; FDA, 2024). A framework is being developed by the USA's National Institute of Standards and Technology (NIST) that focuses on reliability and trustworthiness (FTC, 2020). In 2019, the FDA implemented the "Proposed Regulatory framework for Modifications to AI/ML-based SaMD", in which developers were accountable for informing the FDA of any change in the performance and input. The FDA published the "Artificial intelligence and Machine Learning Software as a Medical Device Action Plan" also known as the "AI/ML SaMD Action Plan" in January 2021 (FDA, 2024).

On March 15, 2024 the FDA published the "Artificial intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together," which is a representation of the FDA's coordinated approach to AI. The paper complements the "AI/ML SaMD Action Plan" and represents a commitment between the FDA's various centers including the Center for Biologics Evaluation and Research (CBER), the Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH), and the Office of Combination Products (OCP), to enhance alignment and share learnings on AI in medical products (FDA, 2024).

The U.S. Food and Drug Administration (FDA) plays a central role in regulating medical devices with AI. The FDA categorises AI based systems and tools as software as a medical device (SaMD), and a risk-based approach is considered in their regulations. The FDA has proposed a Total Product Life Cycle (TPLC) approach to manage the unique features of medical AI. The approach enables AI algorithms to be modified under controlled conditions, thus enabling an evolving AI system whilst ensuring safety and efficacy. The TPLC is an innovative framework that provides flexibility for the AI's nature and places importance on post-market surveillance (Price, 2020).

2.3.2 Europe

On 2 February 2024 the AI Act was approved by the European Council Ministers. This is the first comprehensive regulation on AI by a major regulator throughout the world (European Parliament, 2024). Parliament aims to ensure that AI systems in the EU are governed by human oversight rather than automation, to ensure safety, transparency and respect rights. According to the AI Act, AI systems are classified into four categories based on their risk level:

- Unacceptable Risk: AI systems with risks too high that are considered harmful to people will be banned. These include, but are not limited to, social scoring and biometric identification systems (except for law enforcement purposes).
- High Risk: This is subdivided into two categories:
  1) AI systems that fall into the EU product safety legislation – this includes medical devices
  2) AI systems falling into specific areas requiring registration in the EU database, some of which includes law enforcement, employment worker management and migration.
- Limited Risk: Refers to risk associated with lack of transparency in AI usage. There are specific transparency obligations that are introduced in the AI Act to inform individuals that AI is involved. An example is the use of chatbots, in which humans should be made aware that they are interacting with AI.
- Minimal or no risk: This is AI-enabled video games or spam filters. There are no limitations of use.

The risks of AI systems that are presented must be addressed, for example it may not be possible to determine why the AI system made a decision or prediction and took a particular action. The proposed rules in the Act include setting clear requirements for high-risk AI applications, prohibiting AI applications that propose unacceptable risk, address risks created by AI systems. There are four levels of risk defined in the regulatory framework as depicted in Figure 1, below (European Commission, 2024).

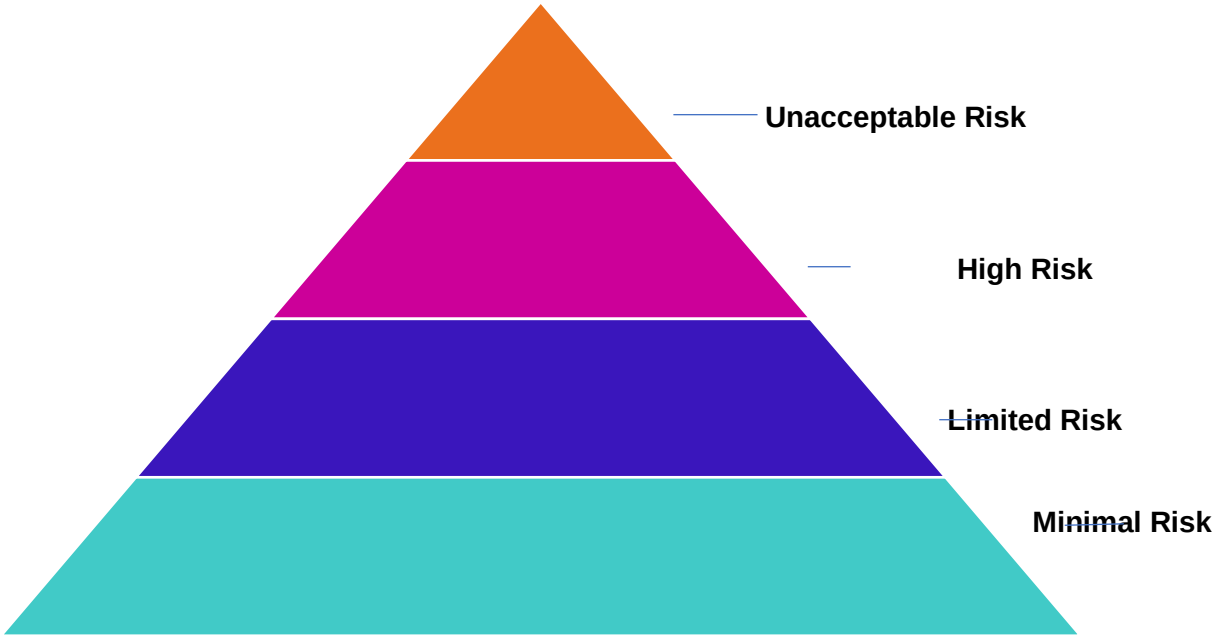


Figure 1: The regulatory framework of the EU AI Act. Defines 4 levels of risk for AI systems.

The European AI Act is a significant step in regulation of artificial intelligence; however, it presents several challenges that could impact on businesses, innovation and its regulation. The AI Act introduces complexity and a compliance burden as there are detailed compliance and documentation requirements, which can be costly for companies especially small and medium-sized enterprises. The Act's stringent requirements especially for the use of AI in high-risk areas, could discourage companies from implementing AI technologies, thus stifling innovation that may have major societal benefits (CCN, 2023). The AI risk classification presents ambiguity and uncertainly to companies, which could delay the use of AI technology and complicate regulatory enforcement, as the understanding of the law may be a challenge for regulators themselves. Another important challenge to highlight is that of Global competitiveness, in which stringent regulations enforced by the AI Act, may disadvantage European companies, when compared to those countries with less stringent regulations, thus hindering the growth of AI in the European region comparative to rest of the world (Hacker, 2023).

Once an AI system is on the market, health authorities are responsible for ensuring that there are robust surveillance mechanisms and post-market monitoring systems in place. Post-market surveillance involves the collection of data from user feedback, operational performance and incident reports. This is to identify trends and risks that were not detected during pre-market surveillance (NSF, 2023).

2.3.3 United Kingdom (UK)

In March 2023, the AI Regulation White Paper was published by the United Kingdom government. The strategy focused on innovation, ethical use of AI and competitiveness internationally. The AI (Regulation) Bill was proposed by Lord Holmes (Conservative peer), which would establish a new body, the AI Authority, for addressing AI regulation in the UK. They would also ensure alignment between existing regulators in the UK. The government announced that primary legislation would be required to regulate AI in the future, however, asserts that it is too soon in the AI technology evolution to legislate successfully. In February 2024, the government proposed measures to support its approach, expanding on the white paper published in 2023, and including guidance to regulators inclusive of regulatory principles. This was welcomed by companies such as Google and Microsoft (Tobi, 2024).

The United Kingdom Data Protection Act, 2018 is an implementation of the General Data Protection Regulation (GDPR). It regulates how personal information is managed by businesses, the government or organisations to ensure that personal information is used lawfully, transparently and for the purposes specified by the requester of the data (UK Parliament, 2024).

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly recognized 10 guiding principles that can aid in the development of Good Machine Learning Practice (GMLP). These guiding principles will help promote the safe and efficacious use of AI in medical devices and machine learning and are outlined Table 2, below (U.S. FDA, 2021).

Table 4: Good Machine learning Practice for Medical Device Development: Guiding Principles (U.S. Food and Drug Administration, 2024)

Good Machine Learning Principles for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Leveraged throughout the product life cycle	Good software engineering and security practices implemented
Clinical study participants and data sets representative of the intended patient population	Training data sets independent of test sets
Reference datasets based upon the best available methods	Model design is tailored to the available data and reflects the intended use of the device
Focus placed on performance of Human-AI Team	Testing demonstrates device performance during clinically relevant conditions
Users are provided clear, essential information	Deployed models are monitored for performance and re-training risks are managed

2.3.4 Japan

Japan have developed AI regulations with a strategy to promote human-centricity, and to implement the principles in human society. The basic philosophy is dignity, diversity, inclusion and sustainability, with a focus on the positive impact instead of the overestimated risks. The government has issued guidelines to emphasize transparency and promote human rights with responsible use of AI (Habuku, 2023). The Ministry of Economy, Communications, Trade and Industry have also established Draft guidelines for AI in Business to unify the guiding principles of the use of AI in Japan and ensure it is safe and secure (National Diet Japan, 2024).

The Pharmaceutical and Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW) are responsible for the regulation of medical devices, including those that are AI-based. In 2019, the “Regulatory Science strategy on AI Utilization in Medical Devices,” explain how AI-based medical devices are evaluated, and developers are required to submit detailed information on the AI’s algorithms (ensuring that they are explainable – regulators can understand how the AI makes decisions). In addition, data sets, validation and training are to be submitted (PMDA, 2019), so that they can demonstrate the device’s safety and efficacy (MHLW, 2020). AI systems are to be continuously monitored, and post-market data collected to ensure AI device safety and effectiveness (Sakai & Aoki, 2020).

Japan is taking a cautious yet advancing approach in the regulation of AI-based medical devices, encompassing both innovation and patient safety. With the dynamic nature of AI and data quality, it is essential that the various stakeholders, such as the regulatory, developers and healthcare professionals maintain ongoing collaboration.

2.3.5 China

The China Electronics Standardization Institute have issued standards and guidelines for AI development, of which highlight the ethics and technical specifications to be considered (CESI, 2021). China has also introduced a New Generation AI Development Plan which outlines the strategic vision aiming to make China a worldwide leader in AI by 2030 (State Council of China, 2017).

In July 2021, the National Medical Products Administration (NMPA), which is responsible for the management of medicines, devices, and cosmetics in China, announced a guideline for the classification of AI-Based Medical devices. China has been making significant strides in the regulation of AI in medical devices. The regulatory framework is overseen primarily by the National Medical Products Administration (NMPA), which is responsible for the supervision and management of medical devices, drugs, and cosmetics in China. The “Regulation on the Supervision and Administration of Medical Devices” was updated to include provisions on AI (NMPA, 2021). Medical devices are categorized into three classes (I, II and III) based on risk, and AI-based medical devices mostly fall into Class II or III, dependent on their intended use and impact on patient safety (Liand & Xue, 2022). The NMPA published the "Guiding Principles for the Technical Review of AI Medical Devices," which highlighted the requirements for registration and clinical evaluation (Zhang & Zhang, 2023). Technical reviews by the NMPA focus on algorithm transparency, data quality, and clinical validation. Evidence is requited to demonstrate reliability, safety and robustness, of the AI system and information on the training and validation of data is to be submitted (Sun, 2023). Clinical trials data would be required for high-risk Class III devices and would have to demonstrate efficacy and safety in practical settings (Chen et al., 2022).

China’s regulatory framework for medical AI is strong, however, it faces many challenges due to the complexity and quick rate at which AI is evolving. Algorithm transparency is reduced due to the black-box often encountered with AI. The Regulators may demand transparency, but this could compromise proprietary technology (Zhou & Zhao, 2022). The lack of standardized criteria

for AI in medical device evaluation could lead to inconsistency. The NMPA has established a post-marketing surveillance system for the reporting of adverse events and risk management of medical AI (Li et al., 2023). There is a requirement for guidelines to be continuously updated to keep pace with the AI innovations, and the NMPA is proactively taking steps to resolve these challenges and ensure safe, effective AI based medical devices.

2.3.6 South Africa

The passing into law of the Medicines and Related Substances Amendment Act 14 of 2015 has resulted in fundamental and extensive changes in the medical device sector in South Africa. The new regulation led to the establishment of SAHPRA, and a licensing and registration system was introduced. This contributed positively to the medical device sector. Prior to the introduction of the MRSA Act, only electromagnetic devices were regulated (Saidi & Douglas, 2018). The regulatory changes introduced by the MRSA Act encompass the licensing requirements for manufacture, distribution, import, export and wholesaling of medical devices, the procedure to register a device and advertising and labelling requirements. Although the MRSA Act includes software in the definition of a medical device, it is not all encompassing of the possible AI applications, such as the use of robotic assistants in a medical setting or software for diagnosis in a clinical setting (Donnelly, 2022). Although AI remains highly unregulated in South Africa, the existing Protection of Personal Information Act does regulate some activities conducted by organisations' such as processing of personal information.

The South African healthcare sector faces unique challenges, including a high burden of disease and disparity in the access to healthcare services. medical AI technologies in devices and diagnostics offer the opportunity to enhance patient healthcare by offering greater accuracy and efficiency in diagnostics, thus reducing costs and enhancing access to healthcare in remote areas (Mabona & Tshabalala, 2021). Although there may be many benefits of medical AI, the rapid pace of AI innovation introduces to unique challenges to the South African healthcare regulatory authority which is responsible for the regulation of medical devices and diagnostics, as the traditional regulatory framework may not be adequate for the advancing AI algorithms. Thus, there is a need for flexible and adaptive regulatory models (Moodley et al., 2019). In addition, with South Africa's diverse population, health authorities must consider the possibility that AI algorithms may reinforce the existing inequalities (Smith & Mkhize, 2020).

2.3.7 International Organisations

The Organization for Economic Co-operation and Development (OECD), a forum in which the government of 37 democracies collaborate to develop policies which promote sustainable economic growth, have developed five value-based principles to promote AI that is innovative, trustworthy, robust, transparent and resects human rights and values (OECD, 2019). The United States Educational, Scientific and Cultural Organization (UNESCO, first-ever global standard on AI ethics – the "Recommendation on the Ethics of the Ethics of Artificial intelligence' – was adopted by all 193 Member States in November 2021. The Recommendation emphasizes the protection of human rights and dignity, transparency and fairness with the importance of human oversight of AI systems. There are extensive Policy Action Areas, for which policymakers may translate this into action in data governance, health, education and societies wellbeing.

2.4 Implications of the POPI Act

A major concern in the regulation of medical AI is the importance of ensuring that it is used ethically, data privacy is maintained and there is no bias and discrimination against patients (Smith & Mkhize, 2020).

In South Africa, the Protection of Personal Information Act (POPIA) was effective from the 1 July 2020. The Act was designed to protect the data processing of personal information, especially in sectors such as healthcare, where this is often involved. POPIA aligns with international data protections laws such as the EU General Data Protection Regulation, which imposes obligations on medical device companies concerning data handling and security (Bawa, 2018). Of key importance is section 71 (1) of POPI which protects patients from being subjected to automated decision making. Companies must ensure that they obtain the consent of patients should it make use of information that is input into an AI system and identifies the patient (Bajwa et al., 2021d). Although the law states this, the conceptualization of privacy based on the right of a patient whether to disclose data must allow for the flow of data for research and innovation, whilst encompassing the respect for the individuals' human rights (Donnelly, 2022).

The European General Data Protection regulation (GDPR), a strong privacy law, that was adopted in 2016 and applied in May 2018, defines and protects individual's rights in the digital era. It outlines the requirements for data processing, and that consent is needed before processing an individual's data, as well as the sanctions for those that have breached the rules. The regulation emphasizes that those who process the data are to ensure that they are transparent and provide

easy to access information to individuals. Although, the law is not specific to AI, it has major implications for AI focused on privacy and the rationale involved in automated decision making (GDPR.eu, 2021). While the GDPR guarantees protection against AI decision-making, the right to explanation (individuals should be able to understand the automated processes of AI technologies) is not outlined in the regulation, instead transparency and accountability is highlighted (Wachter, S. et al., 2017b). There is a need for patients to be given clear information and understand the role of the medical AI in diagnosis of the condition, furthermore, they should be given the right to contest automated decisions, especially in critical situations (Kamara & De Hert, 2020).

There are similar stringent regulatory frameworks to South Africa, across the world. The regulations demand that medical device companies ensure robust data governance, security controls and transparency. In the USA, the Health Insurance Portability and Accountability Act (HIPAA) regulates medical devices that handle the transmission and storage of patient health data, and should there be any data compromise, breach notifications are compulsory (Department of Health and Human Services, 1996). In Canada, the Personal Information Protection and Electronic Documents Act (PIPEDA), required device companies to obtain consent from patents for storage of personal information (Government of Health, 2006). The UK Data Protection Act (DPA) mirrors the GDPR requirements for the processing of data, and companies must show compliance (UK Government, 2018). In China, the Personal Information Protection Law (PIPL), mandates explicit consent for data to be processed, and have places restrictions on cross-border transfers, requiring specific data to only be stored locally (Standing Committee of the National People's Congress, 2021).

2.5 Perceptions of AI regulation

With the growing interest in AI regulation, there remains significant gaps in the various stakeholder perceptions of these technologies. Research should focus on investigating these perceptions, identifying where regulatory frameworks should be strengthened and how stakeholders can be involved in this process (Mkize & Moyo, 2021).

There have been several studies conducted in various countries on the perceptions of regulatory professionals and regulators regarding AI in medical devices. These studies offer insights into how regulatory professionals across various regions perceive the challenges and opportunities of AI regulation in medical devices. The findings emphasise both global similarities, such as the

prioritization of safety and transparency, and key regional differences, particularly regarding regulatory speed, data privacy, and post-market surveillance. Herewith, below, is a review of the key insights, similarities, and differences across countries.

2.5.1 United States (Food and Drug Administration) – Adaptable and Rigorous

Regulatory Professionals in the United States have found the regulation of AI technologies to be flexible yet rigorous. In 2019, a study was conducted to explore the perceptions of the strategy for regulating AI by the United States FDA through the Pre-Certification Program and Total Product Lifecycle (TPLC) framework. Regulatory professionals viewed the Pre-Certification Program as a positive support for innovation and the quickly evolving AI technology. The TPLC is seen as essential in the regulation of adaptive AI technologies, which are often updated and require performance monitoring, thus managing both innovation and safety (Wang, 2021a).

Although the FDA framework offers flexibility, regulatory professionals are concerned about algorithm transparency and the black-box in AI applications, important for decision-making in diagnostics and patient treatment options (Mak et al., 2019). In a study by Benjamens et al., (2020), based on how the FDA copes with regulating the rapid evolution of the AI sector, it was found that the guidelines on AI and machine learning (AI/ML) require refinement, especially concerning AI systems and continuous learning. In addition, the study found that regulatory professionals feel that pre-market approval processes are time-consuming and can limit innovation. In another study by Topol, 2020, in which the focus was on the FDA's evolving approach to the regulation of AI in devices, professionals supported the FDA's emphasis on safety and transparency, however, the challenges noted were the learning aspect and the regulatory control after approval.

2.5.2 European Union (Medical Device Regulation) – Rigorous and slow

Studies conducted on the perceptions of AI regulation in medical devices amongst regulatory professionals in the European Union are based on the Medical Device Regulation (MDR). Regulatory professionals show mixed feelings concerning the MDR and view the framework as "robust and patient-centric", and too rigid for the rapidly evolving AI technology, resulting in concerns regarding reduced compliance by companies (Vokinger et al., 2020). Professionals also see the MDR's main focus on pre-market approval, rather than a focus on the AI technology adaptation post-market approval, as the system evolves and suggests the development of an adaptive regulatory framework that can evolve alongside the AI based medical device (Gerke et

al., 2020). Another key observation by regulatory professionals is the lack of harmonization across the European region. This has created challenges for companies to introduce AI-based medical devices in the EU member states, and therefore a consensus in the AI risk assessment guidelines aligned with innovation and safety is required (Stahl et al., 2021).

2.5.3 China – Prioritisation of Data Security

The National Medical Products Administration (NMPA) regulation of AI is focused on data security and reliability of algorithms (Li & Zhang, 2022), of which regulatory professionals emphasize are critical in the NMPA guidelines (Zhou et al., 2021). Regulatory professionals also view the NMPA's guidelines as having a balanced ethical oversight and favourable for innovation as it emphasises adaptive learning models and software updates, however, they have raised concerns about international standard alignment (particularly when compared to the FDA and MDR) and intellectual property challenges (Wang et al., 2021b). Although the emphasis on algorithm transparency is growing, safety and efficacy remains more prominent (Liu et. L, 2020).

2.5.4 Japan (PMDA) – Regulatory Framework focused on Innovation

In Japan, the Pharmaceutical and Medical Devices Agency (PMDA) created the Sakigake Designation System, which allows for the fast-track of AI-based medical devices and is complimented by regulatory professionals for its balance of safety and innovation (Yamada, 2020). Professionals, however, have noted a need for a better post-market surveillance to track real-time updates in AI technology and to incorporate the adaptive learning model of AI systems, thus ensuring safety in post-market surveillance (Matsuoka et al., 2020). The PMDA uses a risk-based approach to evaluate AI systems, and regulatory professionals have highlighted that such an approach supports the prioritisation of high-risk applications. There are concerns about continuous learning AI models and the pace of regulatory updates (Nagai et al., 2020). Regulatory professionals have also highlighted collaborative regulatory frameworks and a need for international cooperation to foster safety and access AI-based medical devices globally (Kondo et al., 2020).

2.5.5 India and South Korea

In areas such as India and South Korea, the perceptions around the regulation of AI is growing. Regulatory professionals express the need for clearer guidelines on ethical issues and algorithm bias in AI-based medical devices (Basu et al., 2021), and for 'more comprehensive standards' (Patel et al., 2021). In South Korea, the Ministry of Health and Welfare (MOHW) regulatory framework, is perceived as well aligned with other international regulatory frameworks and there is a good collaboration with other countries (Kim et al., 2021).

2.5.6 Key Similarities – Perceptions of AI regulation across countries

Regulatory professionals highlight that the focus of regulation by health authorities should be on patient safety, ensuring that AI-based medical devices are safe and effective. In addition, they have emphasised the need for risk-based classification of medical devices ensuring that high risk systems undergo a rigorous evaluation (Bertolini & Aiello, 2021). Due to black-box AI model, transparency is another global concern and regulatory professionals advocate for comprehensive guidelines on algorithm validation and AI systems that show interpretable results (Rajpurkar et al., 2020). Data privacy in AI systems that makes use of patient data has been emphasized as extremely important by regulatory professionals and essential in the country specific data protection laws (Li & Zhang, 2022).

2.5.7 Key Differences

The key differences as highlighted above are related to Speed of evaluation pathways, post-market surveillance and harmonisation. For speed of evaluation: The US and Japan prefer faster and flexible evaluations, such as the FA Pre-certification Program and Sakigake, whereas in the EU, the MDR is perceived as slower and rigorous, with professionals stating that more agile pathways are required (Bertolini & Aiello, 2021). With Post-Market Surveillance, the EU MDR is more focused on ore-market safety with slower post-market adaptation, whereas the FDA and PMDA strongly focuses on post-market surveillance of AI-based medical device technology (Rajpukar et al., 2020). Global Harmonisation: In the EU, the main concern is regional harmonisation and GDPR compliance, whereas in China and India, there is an emphasis to align with international standards to facilitate market access globally (Li and Zhang, 2022; Basu *et al*., 2021).

2.6 Summary

Artificial intelligence has potential for use in the evaluation of the risk of disease onset, potential treatment outcomes, the alleviation and reduction of complications, continuous patient care, clinical research and drug development (Naidoo, 2022), areas which are pertinent to patient healthcare. The challenge posed is how they should be accessed and approved to ensure their safety, and how best for Regulators to keep adequately informed about these changes, respond and amend regulations accordingly. Although the MRSA Act introduced major changes in the medical device sector, there are no regulations or policies covering the scope of AI and its functionality in medical devices (Townsend et al., 2023b). This presents a new environment requiring regulations that are effective and responsive and should not be under/over-regulated. To address the lack of guidelines and facilitate a stronger self-regulation, it is important to determine the knowledge gaps that exist, and the general attitudes of medical AI in South Africa. The data collected will be analysed and could contribute to the foundational knowledge on how medical devices can be regulated in South Africa.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter describes the study methodology. The study design, sampling, data collection tools and data analysis are detailed, and a rationale for the selection of these study methods is provided.

3.2 Study Design

The study was a quantitative, cross-sectional study that utilised a self-administered survey (Appendix C) to collect data to aid in understanding the knowledge, attitudes and perceptions of the Regulation of medical AI. The survey method was used as it is an efficient means to gather data from a large group of participants. It also allowed for the collection of organized data that could be statistically analysed by the researcher, and ensures consistency in the data collection, thus enhancing the reliability of the results (Babbie, 2021).

3.3 Study population and sample size

The study consisted of surveying the regulatory personnel cohort of device companies in South Africa. For the purposes of this study, regulatory personnel are defined as individuals involved in an organization's adherence to regulatory compliance. This includes regulatory affairs specialists, regulatory affairs pharmacists, associates, assistants, or any other personnel working with product registrations and product lifecycle maintenance within healthcare companies. The entire population will be invited to participate in the study. A convenience sampling technique was utilized to recruit regulatory affairs professionals working within the pharmaceutical and medical device sector. Participants were recruited through the industry association SAMED, and through the social media platform LinkedIn. The reason for selecting this study population is that they are responsible for tracking the ever-changing regulations in which a company distributes its products and advises companies on legal and scientific constraints. There may be more than one response collected per company based on the number of regulatory personnel and responses received. The target population was regulatory professionals from a diverse range of device companies from small and medium sized enterprises (SME) to large enterprises. South Africa has approximately 136 medical device manufacturers (SAMRC, 2022). Most companies are located in three provinces: Gauteng (60), Western Cape (47) and KwaZulu Natal (26). There is a minimum of 136 participants that will be invited to participate, and the response rate will be calculated based on the number of completed responses received.

3.4 Inclusion and Exclusion Criteria

Table 5: Inclusion Criteria and Exclusion Criteria below provides a summary of the criteria and is outlined below.

Table 5: Inclusion Criteria and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Regulatory personnel	Non-regulatory personnel
>80% completed survey	<80% completed survey
Residing in South Africa	Not residing in South Africa

3.5 Data collection tool

Data collection was undertaken with a survey data collection tool (Appendix C). Surveys were sent out to companies by the South African Medical Technology Industry Association, in which the email request was routed to the Regulatory department. The email contained a link to the survey. The number of member companies for which the survey was distributed too, was indicated in the mailing list. The South African Medical Technology (Medtech) Industry Association is an industry association that collaborates with Medtech, device and diagnostic companies to advance patient healthcare ethically and sustainably. They engage with various stakeholders to “promote the interests, knowledge and expertise of members, increase the visibility, credibility and standing of the Medtech industry, advocate to understand policy and improve market access (SAMED, 2023). In addition, Regulatory professionals were reached out and invited to participate in the study via LinkedIn.

The survey was based on a similar study by Ahmed et al., 2022 and questions were adapted to suit the objectives of the study. Data was collected using a self-administered questionnaire. The questionnaire is divided into 5 sections as follows: Section 1 is based on demographic information; Section 2 is a knowledge base section and Section 3 focuses on the Attitudes and perceptions on the regulation of AI. The questionnaires comprised knowledge, attitude, and perception sections. Knowledge statements typically refer to a participant understanding of a topic, for which they had two possible responses in the questionnaire- “yes” or “no”. Attitude and perception statements were subject to responses based on a five-point Likert scale and allowed for one of the following responses: “strongly agree”, “agree”, “neutral”, “disagree” and “strongly disagree”.

The measures of knowledge, attitudes and perceptions were treated as ordinal variables. Attitudes express the level of agreement with a statement and measures the personal views or opinions of a participant on a particular topic. Perceptions, like attitudes, relate to a participant's interpretation of a topic (Trochim, 2020). The Likert type scale was used in the study. This type of scale is ordinal because the categories have a natural order, but the intervals are not equal between them (Bhandari, 2020). Means, percentages and frequencies were used to summarize the data. Although these types of measures are usually concerned with continuous data, their use with ordinal data, presents a simplified overview of the participants responses (Trochim, 2020).

Validity was achieved by determining the content and face validity of the questionnaire. This led to the piloting of the questionnaire among a group of 5 participants, who were not part of the regulatory affairs personnel cohort. These participants are experts in the field of regulatory affairs. Feedback and comments from the test group were used to improve the questionnaire before it was sent to the regulatory affairs personnel cohort. Further reliability testing using the internal consistency method using Cronbach's Alpha analysis was employed (Aithal & Aithal, 2010).

Concepts of reliability (indicates consistency of the measure) and validity (shows the accuracy of the measure) (Middleton, 2022) were used to evaluate the quality of research. To achieve the validity and reliability of the survey, it was distributed to a small group of pharmacists, who were not part of the pharmacist cohort. Feedback from the test group was used to improve the survey prior to it being shared with the pharmacist cohort. A panel of experts reviewed the survey to check that the objectives will be met with the data collection tool. Panel experts are those experts that have practiced in the field for more than 10 years. Cronbach's alpha, a measurement scale of reliability, was used to measure internal consistency, that is how closely related a set of items are as a group (Tavakol, 2017).

3.6 Study procedure

Once the Wits Human Research Ethics Committee approved the study, emails were sent out through SAMED, inviting potential participants to join the research. These invitations included a brief overview of the study and an attached participant information sheet (see Appendix D). The email contained a link directing participants to the online questionnaire on Google Forms. The email also outlined the time frame for completing the questionnaire and emphasized that participation was voluntary. The questionnaire took approximately 10-15 minutes to complete,

and strict confidentiality was upheld throughout the study; no identifiable information was recorded.

3.7 Data Analysis and Data Management

A total of 106 responses were received. All the data was stored on a cloud and was password protected. Data was transferred to Microsoft Excel to allow it to be organized, cleaned and to be compartmentalized, allowing for easier evaluation and analyzation. The data collected was described using descriptive statistics (Trochim, 2020. A data set is described as a "collection of responses or observations from a sample or entire population" (Bhandari, 2020). Graphs, percentages, means and frequencies were used to give a well-rounded and simplified view of the data. Inferential statistics were used to expand on the results identified to better understand the meaning behind observations, draw conclusions and make predictions based on the data (Trochim, 2020).

Access to data was kept confidential and shared with the researcher and supervisor. The results were analyzed using basic statistics (such as total numbers and percentages). The significance level was set at 0.05. A subgroup analysis was performed using Kruskal-Wallis. The Kruskal-Wallis is a non-parametric method for testing whether samples originated from the same population. A chi squared test was done to observe whether there were significant differences among response categories. Following this test, a post-hoc pairwise Mann-Whitney U test with Bonferroni correction for multiple tests was done in order to investigate variances in knowledge and attitudes amongst regulatory personnel. For all tests the level of significance was set to p-value ≤ 0.05. Descriptive statistics were conducted on the data set using both Microsoft excel and STATA- ® 18.0 Edition

CHAPTER 4. RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents the findings from the survey carried out to assess the knowledge, attitudes, and perceptions of medical AI among regulatory professionals in South Africa. The study was conducted for the purpose of assessing the level of knowledge and understanding of medical AI applications, as well as the challenges linked to the regulation of such technologies in the healthcare sector.

Data was collected through a self-completion survey and analyzed by descriptive and inferential statistical methods. These results will highlight the extent of knowledge and adoption of AI within the regulatory environment, as well as the concerns professionals have with regard to the integration of AI in medical devices. This chapter will outline the demographic profile of the respondents, their knowledge of AI applications, perceived regulatory challenges, and general attitudes toward AI in the future of healthcare. The recommendations are based on findings relating to the adjustments that should be made to the regulatory framework in South Africa to accommodate AI integration in the medical device sector.

4.2 Validity and Reliability

This questionnaire, based on face and content validity, was established to ensure that the instrument served as a valid measure of knowledge, attitudes, and perceptions of medical AI in regulatory professionals based in South Africa. Face validity assessed whether the questions seemed clear and relevant to the purposes of the survey. A panel of five regulatory experts reviewed the questions and found that a majority of the questions were appropriate, though some needed minor rewording for clarity. For example, demographic questions were highly rated, such as questions about age or gender. The content validity examined whether the questionnaire completely explored relevant issues concerning medical AI and its regulation.

Indeed, experts agreed that the survey from a general point of view addressed the main areas of concern regarding AI applications and use, regulatory challenges, and ethical implications in healthcare. Indeed, from responses, there was a general feeling among those who answered the survey that it was rather informative and very relevant; there were no major topics that the questionnaire had not covered. All respondents rated the overall comprehensibility of the survey as high, finding it easy to understand. The only minor suggestions for improvement concerned

the refinement of some of the technical terms used in certain questions to alleviate ambiguity. Overall, the questionnaire was very valid, with positive feedback confirming that it captured the intended information accurately and was appropriate for the target audience.

In this study, 136 participants were invited to participate, and a total of 106 participants provided feedback. This resulted in a response rate of approximately 77.94%. The response rate was calculated by dividing the number of participants who provided feedback (106) by the total number of invited participants (136) and then multiplying the result by 100 to express it as a percentage. This high response rate suggests a strong level of engagement from the invited participants.

To test for Reliability, Cronbach's Alpha was utilised, the value of which was 0.90. The high value indicated great internal consistency, indicating that the Likert scale reliably measure related construct (attitudes and perceptions toward medical AI). According to George and Mallery (2003), a Cronbach's Alpha value above 0.9 is considered "excellent", further affirming the reliability of the Likert scale. Similar findings were observed in a study by Chew et al., (2021), which examined 350 healthcare professionals in Singapore, to assess their perceptions of AI integration in clinical settings. In this study, the Likert scale used to measure attitudes toward AI achieved a Cronbach's Alpha of 0.88, which indicated strong internal consistency and supported the reliability of the tool.

4.3 Demographics

The demographic characteristics of the respondents have been summarized in Table 4. The variables collected in this study were age distribution (age bands), gender, level of education, and position/title.

4.3.1 Age Distribution

The dominant age group of the respondents fell within the age bracket of 31-40 years, reflecting 41.5% of the total sample. The immediate next greater category is that of the 18–30-year-olds, making up 32.08%. The third category consists of the 41–50-year-olds, representing 17.92% of the total number, while the last percentage, which consisted of the 51–60-year-olds, was 6.6%.

4.3.2 Distribution of Gender

There was a bias in the gender distribution towards females, as 72.6% of the responding participants identified their gender as female. Only 27.4% of the responding individuals were males. This would therefore suggest a gender imbalance within the profession of regulatory affairs

in the healthcare industry within South Africa-the industry is dominated by females. A study by Townsend et.al. highlights key points showing that there is an underrepresentation of women working in AI and that gender imbalances are a global issue differing across countries (Townsend & Saidi, 2023a). With the introduction of AI in the medical device sector, the representation may change over time, given the gender demographics of the regulatory field within South Africa.

4.3.3 Level of Education

The majority of respondents held postgraduate qualifications, 60.4% of participants reported this level of education. This therefore means the sample population can be described as highly educated professionals, of which their advanced educational background contributes to a heightened knowledge of AI regulatory frameworks. In a similar study by Ahmed & Ali (2020), on perceptions of AI among healthcare professionals in Pakistan, the findings highlighted that a higher level of education links to a better understanding of the ethics and regulations of AI. In contrast, however, in a study done in Germany by Grote & Berens (2020), on the ethics of algorithmic decision-making in healthcare, while discussing the ethical implications, the study suggested that healthcare professionals, even with advanced education lacked exposure to AI regulatory frameworks, largely because the field is still relatively new.

The implications of this analysis for South Africa highlight key elements: The representation of highly educated regulatory professionals suggests a strong foundation for leadership in the AI regulation within the healthcare sector, which could facilitate enhancing the ethical and legal frameworks for AI within Africa. Comparing the results in South Africa to those from Ahmed and Ali (2020) in Pakistan, shows that education levels can drive a better understanding of AI's ethical and regulatory concepts. By contrast, however, in a study based in Germany by Grote and Berens (2020), the findings indicated that highly educated professionals lacked exposure to AI regulatory frameworks and indicated that advanced education does not guarantee familiarity with AI regulatory frameworks, showing that there is a gap in the curriculum or professional exposure to this emerging field. Their study serves as a reminder that both education and ongoing professional development on the regulation of medical AI is important for the regulatory professional.

Table 6: Demographic Profile of Respondents (n = 106)

Demographic Attribute	**Category**	**Percentage**
Age Distribution	18-30 years	32.08% (34)
	31-40 years	41.50% (44)
	41-50 years	17.92% (19)
	51-60 years	6.60% (7)
Gender Distribution	Female	72.60% (77)
	Male	27.40% (29)
Education Level	Postgraduate Qualification	60.40% (29)
	Graduate	36.80% (64)
	Doctorate	2.90% (3)
Title	Various incl. Deputy Responsible Pharmacist, Medicine registration officer, QA/RA manager, Regulatory Affairs officer, senior regulatory affairs specialist, regulatory affairs operations lead	0.94% (1) each
	Head of Regulatory Affairs	5.66% (6)
	Regulatory Affairs Specialist	16.04% (17)
	Responsible Pharmacist	1.89% (2)
	Regulatory Affairs Associate	10.38% (11)
	Regulatory Affairs Manager	15.09% (16)
	Authorised Representative	5.66% (6)
	Regulatory Affairs Pharmacist	17.92% (19)

4.4 Knowledge of AI

4.4.1 Respondents with AI knowledge

An overwhelming majority, 99.06% of the total respondents, indicated that they were familiar with AI. From this, an incredibly high percentage of all regulatory professionals are at least aware of AI as a concept. Majority of participants (86.8%) understood the definition of machine learning, whilst 80.2% of participants selected the correct answer for the definition of deep learning (Table

5). The near-universal familiarity with AI points toward the growing importance and relevance that AI is assuming in the regulatory landscape (Donnely, 2022).

Table 5: Participants knowledge about AI in South Africa (n = 106)

Items	Yes	No
1. Do you know what AI is?	99.10% (105)	0.90% (1)
2. Do you know of any applications of AI in the medical field	46.20% (49)	53.80% (57)
3. Does your company incorporate medical AI in its devices	23.60% (25)	76.40% (81)
4. Do you believe AI will pose many challenges to Regulators	79.40% (84)	20.60% (22)
5. Is this a precise definition of machine learning: A field of artificial intelligence in which machines are able to imitate intelligent human behavior and perform complex tasks in a way in which is similar to how humans solve problems?	86.80% (92)	13.20% (14)
6. Can deep learning be defined as the use of an artificial neural network to reach accurate conclusions without human intervention?	80.20% (85)	19.80% (21)
7. Does South Africa have any laws governing AI in Medical Devices?	18.90% (20)	81% (86)
8. Which elements of medical AI pose the greatest regulatory challenges? Note: more than one option may be selected.		
• Safety and Efficacy	68.90% (73)	31.10% (33)
• Data Privacy	63.20% (67)	36.80% (39)
• Algorithm Transparency	50.90% (54)	49.10% (52)
• Continuous Learning and Adaptation	52.80% (56)	47.20% (50)
• Clinical Trial Design	40.60% (43)	57.80% (63)
• International Harmonization of Regulations	56.60% (60)	43.40% (46)
• Other:	0	0

Of the 23.6% of respondents who reported the use of AI applications in their companies, the selected areas of application included cardiology, diagnostic imaging, ophthalmology, orthopedics, and diabetes. Participants were asked if they know of any applications of AI in the medical field, and the majority of 53.8% responded “No’. From the 46% who knew of such applications, the following were included in the listing: AI driven genomics, Neuralink, Diagnostic

imagery, Google diagnostics, ChatGPT, Artemis, Smart-watches, Medical Imaging and remote surgery.

The results indicate a high degree of consistency in participants level of understanding of medical AI. For example, responses to questions such as "*Do you believe AI will pose many challenges to regulators*?" and "*Does South Africa have any laws governing AI in medical devices?*" showed no significant variation, suggesting that regulatory professionals may have similar levels of knowledge or perspectives on AI in South Africa. The lack of significant differences could also signal a general agreement on basic AI concepts and their relevance in healthcare. However, it is possible that the binary nature of the responses ("Yes" or "No") limited the ability to uncover more detailed opinions. Previous studies emphasize the importance of context and stakeholder diversity in assessing perceptions of AI (Vellido, 2019; European Commission, 2020). Future research could benefit from more detailed response options or incorporating qualitative research methods. Additionally, the results show a need for increased education and conversation on the role of AI in healthcare, with particular attention in its regulation and ethical implementation.

The results of the statistical tests, an analysis and the implications thereof give further insights into this study. The Kruskal-Wallis test was employed to examine to assess differences in the distribution of "Yes" and "No" responses across different items assessing AI knowledge. To explore the potential variations further, and the possibility of differences between specific pairs of items post-hoc pairwise Mann-Whitney U tests were conducted with Bonferroni correction to account for multiple comparisons. The findings of the Kruskal-Wallis Test revealed a significant difference across all items ($p<0.05$, Appendix F, Table A), indicating a variance in how regulatory professionals responded to the questions assessing knowledge of AI.

Key insights from the study showed that there was a high familiarity with basic AI concepts, as nearly all respondents (99.1%) knew what AI is (Mann-Whitney $U=3.0$, $p<0$, Bonferroni $p<0.001$) (Appendix F, Table B). However, practical knowledge is less robust; only 46.2% are aware of AI applications in the medical field (Mann-Whitney $U=450$, $p=0.005p$, Bonferroni 0.0350), and a mere 23.6% reported organizational use of AI in devices (Mann-Whitney $U=600$, $p=0.09$, Bonferroni 0.630) (Appendix F). The percentage of professionals that indicated that no regulatory frameworks exist for AI in medical devices in South Africa was 81%, and for technical definition understanding, 86.8% correctly identified the definition of machine learning (Mann-Whitney $U=125$, $p<0.001$, Bonferroni <0.001). The Kruskal-Wallis test underscores notable variations in

the knowledge of regulatory professionals. These gaps emphasise a divide between basic knowledge of AI concepts and detailed regulatory knowledge, which is similar to the findings of a study by Viale et al., (2023), conducted on 4006 European citizens. The findings of this particular study across eight countries: France, Germany, Italy, Netherlands, Poland, Romania, Spain, and Sweden, found high levels of AI knowledge but low self-reported competency and understanding of AI technologies and regulations (Viale et al., 2023).

To evaluate whether the distribution of "Yes" and "No" responses deviated from expected frequencies, a Chi-Square Test was done, indicating that none of the questions showed a significant result ($p>0.05$), suggesting no unexpected deviation from observed response patterns. The distribution of responses (e.g., high "Yes" responses for basic AI knowledge vs. low "Yes" responses for regulatory knowledge) mirrors findings from a study conducted in 2023 be the Pew Research Center, in which a survey revealed that while 90% of Americans have heard about artificial intelligence, only 33% have significant exposure to it. Moreover, just 30% could accurately identify specific AI applications, indicating a lack in deeper understanding of AI's practical uses.

This study shows that there is a critical need to address disparities in knowledge and regulatory knowledge among South African professionals. Bridging these gaps will elevate effective oversight, compliance, and innovation in the rapidly evolving field of AI in medical devices.

4.4.2 Respondents with no AI knowledge in the medical field.

To contextualise the findings of the study, it was compared to studies done in other countries. There was a high percentage of respondents aware of the current regulations of medical AI in South Africa, of which 81 % indicated that there are no laws governing the technology. In a study conducted in the United States by Benjamed, Dhunoo, and Mesko (2020), they found that there is a significant awareness about the FDA regulatory framework on AI amongst healthcare professionals. In the European union, research by Muehlematter, Daniore and Vokinger (2021), indicated a general knowledge of the EU’s MDR and the proposed AI Act. The comparative findings emphasis a need for South Africa to implement medical AI regulations. By drawing on the regulations and experiences from other countries, as well as fostering stakeholder engagement, a strong regulatory framework for medical AI can be established in South Africa.

Despite this high knowledge of AI, 53.7% admitted to the fact that they did not know any specific applications of AI in the field of medicine. In a similar study by Ahmed & Ghanim, 2023, the study evaluated the knowledge attitude and perceptions among 875 pharmacy students and faculty members from six Middle Eastern countries. The findings uncovered that 92.6% were aware of AI technology, only 39.5% understood its concepts. The study highlighted the importance of integrating AI education into Pharmacy curricula. This, therefore, exposes a gap in practical knowledge because more than half of the participants were not familiar with the various ways in which AI is put into practice in the health, diagnostics, or medical devices industries. Targeted education and knowledge of the practical use of AI in medicine seem required (Bajwa et al., 2021c). In another study, evaluating knowledge and attitudes towards AI and ChatGPT, conducted in Japan on 113 fourth-year pharmacy students, the significance of AI education to ensure effective use of AI tools is emphasized. Approximately 19.5% had prior exposure to ChatGPT, and 42.5% were able to describe it. General AI concepts such as “machine learning” were recognized by 83.2 % of students. Comparatively, in this thesis, 86.7% of respondents understood the definition of "machine learning," highlighting a higher level of familiarity with this foundational AI concept (Tanaka et al., 2023).

4.5 Adoption and Regulatory Challenges

4.5.1 Insufficiency of Laws Governing AI

The results from the study indicated that 81% of the participants reported that there is no regulatory framework for AI in medical devices in South African. While there is some regulation, especially in the broader field of medical devices, these are not sufficiently developed to meet the challenges that AI may present. This acknowledgment suggests the need for legal frameworks in South Africa that take into consideration such concerns as AI-driven decision-making, liability, and ethical standards (Donnely, 2022).

A vast majority, 79.4%, felt that AI presents quite a significant number of challenges to regulators on issues related to data privacy, algorithm transparency, and the complexity surrounding AI systems. In terms of regulatory challenges, safety and efficacy were identified as the most critical concern, with 68.9% agreement (Mann-Whitney U=400.0, p=0.004, Bonferroni 0.0280). Artificial intelligence introduced within the medical settings presents special regulatory challenges, whereby it is a new area to have frameworks and guidelines owing to the need for safety and assurance in its applications. Other challenges, such as data privacy (63.2%, Mann-Whitney U=480.0, p=0.008, Bonferroni 0.0560), algorithm transparency (50.9%, Mann-Whitney U=520.0,

p=0.06, Bonferroni 0.420), and international harmonization of regulations (56.6%, Mann-Whitney U=460.0, p=0.01, Bonferroni 0.070), showed trends but did not reach statistical significance after correction. These results emphasize the need for clear regulatory frameworks prioritizing safety and efficacy, as well as data privacy, while addressing the evolving nature of AI systems. Targeted training and capacity building are necessary to equip South Africa's regulatory professionals to efficiently manage the complexities of AI-driven medical devices.

The findings of the study indicated a high percentage of challenges in specific aspects of the regulation of medical AI. This was compared to studies conducted in other countries such as the USA and EU and revealed shared regulatory challenges. In the U.S., a survey on 500 participants by by Fleming et al., Safety and Efficacy was seen as the greatest challenges with a percentage of 75,2 %, followed by Data Privacy (16.8 %), Algorithm Transparency (62.3%), Continuous learning (60.4), Clinical Trial Design (48.9%) and International Harmonization (62.1%). Taddeo & Floridi (2022), conducted a study on 12 countries in the EU, and the order of challenges by percentage followed the same pattern as that in the US. Findings within this study for South Africa show that the country reflects global trends in challenges like Safety and Efficacy (68.9%), Data Privacy (63.2 %) and International Harmonization (56.6%). Lower concerns in Algorithm Transparency (50.9%) and Clinical Trial Design (40.6%) were observed. The studies highlight the complexity of medical AI regulation, as well as the requirement for tailored harmonized regulation to address these challenges, which will need cooperation among various stakeholders – regulators, industry, and developers.

4.6 Attitudes Towards AI in Healthcare

Most participants (86.6 %) perceived that AI positively influences health care delivery in terms of diagnostics and patient monitoring. This suggests optimism that the implementation of AI will lighten the workloads of clinicians and expedite and enhance the accuracy of medical decision-making. Table 6 below shows the attitudes and perceptions of regulatory professionals towards AI in healthcare.

For a measure of the Central Tendency (mean, median and mode), and Variability (standard deviation (SD) and interquartile range (IQR)), statistical tests were conducted to derive further insights, these are highlighted in Appendix F, Table C. Most statements had a mean and median value of 3.79 and 4.49, indicating that most participants generally agree or strongly agree with the statements. For example, AI is essential in the medical field "has a mean of 3.70 and median

of 4.0, reflecting general agreement. “International harmonization of medical AI regulations" has the highest mean (4.49) and median (5.0), suggesting a strong consensus on its importance. This reflects regulatory professionals’ recognition of the value of AI in advancing healthcare. The high values for "AI essential in radiology and pathology" and "AI has great potential for use in medical devices" further reflect professionals' confidence about AI's application in medical devices. The mode for most statements is 4 (Agree) and 5 (Strongly Agree) indicating a strong consensus.

The SD values range from 0.91 to 1.14, showing relatively low variability in responses. This suggests participants share similar views on most statements. The statement "AI will replace physicians in the future" had a higher deviation of 1.14 indicating a greater disagreement. IQR values between 1.0 and 2.0 further confirm that responses are centred close to the midpoint. "AI will replace physicians in the future" has the lowest mean (2.12) and median (2.0) and the widest variability (high SD and IQR). This indicates less consensus or scepticism among regulatory professionals regarding this statement. The statement "AI use in healthcare administrative work will have to comply with data privacy laws" and "AI in medical devices pose a higher risk" findings were a high mean and median close to "Agree" or "Strongly Agree") with low variability (SD = 1.04, IQR = 1.00). This suggests professionals’ knowledge of the regulatory complexities of medical AI, and an agreement that regulatory oversight is critical to ensure AI's safe integration into healthcare.

Statistical tests were run on the data and yielded the following results: Kruskal-Wallis test statistic of 27.86, p-value: 1.33×10^{-5}. The low p-value ($p < 0.05$) indicated a statistically significant difference in the distribution of responses across the categories. The Kruskal-Wallis findings align with the Chi-Squared test results (Appendix F, Table B), confirming the observed trends of agreement and disagreement within the dataset. This analysis provides comprehensive insight into the regulatory professional’s attitudes and perceptions of AI. Statements like "*AI is essential in the medical field*" (Chi-Squared statistic = 38.72, $p < 0.05$) and "*AI has great potential for use in medical devices for diagnosis, prognosis, and treatmen*t" (Chi-Squared statistic = 95.79, $p < 0.05$) showed a high significance of agreement, with a majority of participants strongly agreeing or agreeing. These findings align with global studies by Mesko et al., (2020), which emphasize the critical role of AI in improving healthcare outcomes and enhancing efficiency. A comparable study carried out in the United States by Benjamed, Dhunoo, and Mesko (2020) revealed healthcare professionals' significant consensus on the potential of AI to enhance diagnostic

accuracy and personalise treatments. These findings highlight a shared global acknowledgement of AI's potential transformative impact on healthcare.

Conversely, statements such as "*AI will replace physicians in the future*", shows a higher distribution of "Disagree" or "strongly disagree", which indicates skepticism about AI's role in replacing healthcare professionals. While many participants disagreed that AI will replace physicians (Chi-Squared statistic = 41.45, $p < 0.05$), a notable minority showed neutral or supportive views. This indicates varied perspectives on AI's role, suggesting its potential to complement, rather than replace healthcare professionals. This finding aligns with research by Mesko et al., (2020), who emphasise that AI is more likely to augment human expertise than entirely replace it. Muehlematter, Daniore, and Vokinger (2021) similarly note the importance of balancing AI's capabilities with human oversight in clinical settings.

The findings highlight a strong consensus on the need for regulatory harmonization, as demonstrated by the statement "*The international harmonization of medical AI regulations is essential*" (Chi-Squared statistic = 164.28, $p < 0.05$) (Appendix F, Table D). This is consistent with Muehlematter, Daniore, and Vokinger (2021) study, which places emphasis on the importance of frameworks like the EU's MDR and the proposed AI Act in endorsing the safe and effective use of AI in medical devices. Privacy concerns remain significant, as seen in responses to the statement "*AI use in healthcare administrative work will have to comply with the data privacy laws in South Africa, there are serious privacy concerns with the use of AI*" (Chi-Squared statistic = 65.51, $p < 0.05$). These concerns align with observations by Benjamed, Dhunoo, and Mesko (2020) in the United States, where professionals emphasize the need for robust data protection measures to ensure patient confidentiality. Additionally, statements regarding accuracy and safety of medical AI (e.g., "*AI in medical devices pose a higher risk of deviations from accuracy, safety, and performance*") displayed significant variability, underscoring emphasize the importance of aligning South African regulations with international regulatory frameworks, while addressing local challenges to ensure AI's seamless integration into healthcare.

This has not completely alleviated skepticism about the integration of AI into the healthcare system. While many were optimistic regarding AI's role in promoting a reduction of time taken for clinical tasks, such as radiotherapy planning, as many as 39.6% of the respondents remained neutral on whether AI resulted in better patient treatment outcomes. In a study by Topol (2019), it was highlighted that while AI shows promise in diagnostic and administrative activities, many

healthcare professionals are apprehensive about improving patient outcomes, contrasted to the greater benefits from the technical capabilities. Conversely Kelly et al., (2021) documented improvements in radiology and pathology with the integration of AI, including improved diagnostic accuracy. This contrasts with the findings of Bajwa et al., (2022), where 30.19% of respondents believed that AI could not be easily integrated into current regulatory frameworks, indicating the challenge of accommodating these innovations effectively.

Table 6: Participants Attitudes and Perceptions Towards AI in Healthcare in South Africa (n = 106).

Attitudes and Perceptions Statement	**Response**				
	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
AI is essential in the medical field	25.5% (27)	33% (35)	30.2% (32)	8.5% (9)	2.8% (3)
AI use in healthcare administrative work will have to comply with the data privacy laws in South Africa. There are serious privacy concerns with the use of AI	40.6% (43)	37% (39)	14.2% 15	4.7% (5)	3.8% (4)
AI has great potential for use in medical devices for diagnosis, prognosis, and treatment.	46.2% (49)	39.2% (42)	9.4% (10)	1.9% (2)	2.8% (3)
AI will replace physicians in the future	2.8% (3)	12.3% (13)	17% (18)	30.2% (32)	37.7% (40)
The international harmonization of medical AI regulations is essential.	67.9% (72)	20.8% (22)	6.6% (7)	1.89% (2)	2.83% (3)
AI in medical devices pose a higher risk of deviations from accuracy, safety and performance of medical devices	13.2% (14)	13.2% (14)	39.6% (42)	24.5% (26)	9.4% (10)
A multi-stage regulatory review model by health authorities will be required to address safety, quality and efficacy concerns as AI systems are adaptive.	50.9% (54)	31.1% (33)	15.1% (16)	1.89% (2)	0.94% (1)

Table 6: Participants Attitudes and Perceptions Towards AI in Healthcare in South Africa (n = 106).

Attitudes and Perceptions Statement	**Response**				
	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
AI will be essential in the fields of radiology and pathology	36.8% (39)	46.2% (49)	14.2% (15)	0.94% (1)	1.9% (2)
The regulation of AI will be a burden to healthcare authorities	26.4% (28)	24.5% (26)	21.7% (23)	17% (18)	10.4% (11)
The regulatory professional's role is important in the application and evaluation of medical AI.	57.6% (61)	32.1% (34)	8.5% (9)	0.94% (1)	0.94% (1)
You have a keen interest to work on medical AI in the future	44.3% (47)	32.1% (34)	17.9% (19)	4.7% (5)	0.94% (1)

4.6.1 Comparison of the participants' attitude and perceptions of AI

The Kruskal-Wallis test was used to compare the distribution of responses for the different survey questions in the attitude section. All questions showed a statistically significant difference in the response to the statements, except for 3 statements ($p > 0.05$): '*AI use in healthcare administrative work will have to comply with the data privacy laws in South Africa'*, '*There are serious privacy concerns with the use of AI*, '*AI will replace physicians in the future'*, and '*The regulatory professional's role is important in the application and evaluation of medical AI'.* Given the Likert scale nature of the responses (which are ordinal), the Kruskal-Wallis test provided a robust means to study the differences in participants attitudes without assuming that the data is normally distributed.

The results from the Kruskal-Wallis test may indicate that participants in South Africa have a similar perception on these topics, regardless of their personal or professional backgrounds. For these statements, there might be a consensus among respondents that privacy and compliance related to medical AI are crucial in its use. Given South Africa's Protection of Personal Information Act (POPIA), which mandates stringent data protection laws (South African Government, 2013), it is likely that participants are more attuned to the importance of adhering to data privacy laws within the country. Since privacy laws in healthcare are generally recognized concerns in South Africa, participants may share similar views on these matters, leading to less variation in their responses. Similar concerns have been noted in other countries, where the regulatory framework

for AI is more comprehensive. For example, Dinev and coworkers reported that HCPs in Saudi Arabia are more likely to express concerns for the adequacy of AI data protection measures and patient confidentiality breaches (Dinev & Hart, 2006). In a study by Voigt and Bussche (2017), it was revealed that healthcare professionals in European countries are cautious about incorporating AI technology in their practice, due to the rigorous compliance requirements and penalties because of GDPR data breaches.

4.6.2 Evolving Role of Regulatory Professionals

The statement, '*The regulatory professional's role is important in the application and evaluation of medical AI'*, showed that participants agreed on the importance of regulatory oversight of medical AI. The consensus highlights the need for regulatory oversight in this emerging field. The role of regulatory professional's oversight will become more important as the use of AI in healthcare is increased. Regulatory professionals will play a key role in ensuring compliance with safety and performance standards and shaping the emerging regulatory frameworks that will address the challenges of medical AI. This will be inclusive of data integrity, bias mitigation, and the evaluation of algorithms. This is especially important in South Africa, where SAHPRA plays a key role in safety, performance and compliance of healthcare products (SAHPRA, 2021). Given this context, participants of the study might have displayed similar views on the important role of the regulatory professional in oversight of AI applications in healthcare.

The role of regulatory professionals within South Africa will become increasingly important as the adoption of AI is increased in healthcare. Regulatory oversight will ensure that these technologies are compliant to regulations. As the use of medical AI is enhanced, the role of the regulatory professional will progress to encompass several key responsibilities. These may include and not be limited too, ensuring compliance (data integrity and bias mitigation) and the evaluation of the algorithm's robustness. Moreover, the regulatory professional's role will be significant in shaping regulatory frameworks that can effectively address the challenges posed by medical AI. The role of the regulatory professional will be significant in developing public trust and enabling transparency in decision-making related to medical AI. SAHPRA has a responsibility and mandate to ensure all healthcare products within South Africa to meet safety, efficacy and compliance standards (SAHPRA, 2021). However, the regulatory framework for AI is underdeveloped, and this poses a major challenge for the effective governance of medical AI.

The lack of a regulatory framework for medical AI in South Africa, and the gap thereof, could hinder the acceptance of AI in healthcare and the management of risk, safety and quality of AI-driven devices. In contrast, other countries have established more comprehensive regulatory frameworks. In the USA, the FDA has implemented guidelines for the regulation of Software as a Medical Device (SaMD) and AI-based technologies, including frameworks for premarket review, post-market surveillance, and adaptive algorithms (FDA, 2021). The EU, MDR and AI Act, have outlined specific requirements for classification, post-market surveillance and adaptive algorithms (FDA, 2021). The UK's MHRA, have tailored AI regulatory frameworks emphasising transparency and patient safety (MHRA, 2021).

The results of this study were compared with a study by Wittal et al., (2023) in which two online surveys were conducted in November 2021 on participants in Germany aged >18 years. The surveys had identical procedures but different samples on the public perception of knowledge of either Artificial Intelligence or the use of data in healthcare. Wittal et al., surveyed 1,001 adults in Germany, finding that only 23% could provide a clear definition of AI, and 56% had encountered AI in healthcare, with most unprompted examples being assistance during operations (40%) and imaging diagnostics (21%). In contrast, this study targeted 106 South African regulatory professionals, where 99.06% were familiar with AI, but only 46.2% were aware of its healthcare applications, and just 23.6% reported using medical AI in their organizations. Both studies highlighted concerns around safety, efficacy, data privacy, and algorithm transparency. However, this study uniquely identified a significant regulatory gap in South Africa, with 81% of respondents emphasizing the need for stronger regulatory frameworks. While Wittal et al., focused on public perception, this study underscores the need for targeted education and regulatory frameworks to address these challenges, especially in the South African context where local regulations on Artificial Intelligence are to be developed.

4.7 Conclusion

The findings indicate that while there is a high general knowledge of AI, there is an appreciable knowledge gap regarding specific applications in medical devices that must be addressed. The study findings highlight the professional's acknowledgement of the importance for a robust regulatory system, especially in concerning data privacy, safety, and efficacy, indicating this as a priority area for regulatory authorities. Furthermore, the existing legal frameworks in this respect are incapable of dealing with these newly arising problems. New regulations and guidelines will be required for safe and productive integration into healthcare, and SAHPRA will play a key role

in ensuring this. This can be supplemented by increased training and education about AI applications (Naidoo 2022). In addition, the strong agreement on harmonising international regulations on AI in medical devices indicates a need for collaboration between regulatory bodies worldwide to ensure uniform standards and requirements for AI in healthcare.

CHAPTER 5. CONCLUSION AND RECOMMENDATION

5.1 Introduction

The rapid advancement of artificial intelligence in healthcare introduces both exciting opportunities and challenges for regulatory professionals. In South Africa, the adoption of AI technologies in the medical field has raised critical concerns about the adequacy of regulatory frameworks to manage these innovations. Regulatory professionals, who play a key role in ensuring the safety and efficacy of medical technologies, must not only comprehend the potential benefits of AI but also address the ethical, legal, and technical challenges associated with their integration into healthcare systems. This study aimed to explore the knowledge, attitudes and perceptions of regulatory professionals in South Africa regarding the use of AI in medical devices, and to identify the gaps in their understanding and the regulatory frameworks needed to facilitate the responsible use of AI in diagnostics and treatment.

5.2 Conclusion

In conclusion, the study demonstrates that while participants have knowledge of what artificial intelligence is, they exhibit a significant gap in their understanding of specific AI applications in healthcare. Regulatory professionals are optimistic about the potential of AI to improve healthcare efficiency, yet they remain cautious about its integration into regulatory frameworks. There is a clear need for more comprehensive legislation to govern the use of AI in medical devices, as current laws are deemed insufficient by many respondents. The findings suggest that targeted education, regulatory updates, and further research are essential to ensure that AI can be effectively integrated into the healthcare sector. In addition, it is critical to address the ethical, legal, and technical challenges with AI in healthcare (Naidoo, 2022; Townsend & Saidi, 2023b). The study further highlighted that the lack of a comprehensive framework in South Africa poses a major challenge. By learning from international best practices and addressing the unique healthcare environment within South Africa, SAHPRA can create a regulatory framework that ensures the safety and efficacy of medical AI whilst also fostering innovation and equitable access.

5.3 Study Limitations

Numerous limitations should be considered in the interpretation of the results of this study. First, the sample size (106 participants) may not be fully representative of all regulatory professionals in South Africa, potentially limiting the generalisability of the results. In addition, the study was quantitative and did not include qualitative data assessment. As the participants knowledge, perceptions and attitudes towards medical AI could be influenced by the professional experiences and personal opinions, the self-reported type of questionnaire used in the study, may reflect biases. Furthermore, the study did not investigate the regional or institutional differences that might affect the adoption and regulation of AI technologies across South Africa. Naidoo, 2022, outlines that the strength of a study's findings can be enhances by incorporating a larger sample size. This can be considered in future studies on the knowledge, attitudes and perceptions of medical AI.

5.4 Recommendations for this study

Based on the study design, findings, and scope of this thesis, the recommendations outlined herein are made to improve the understanding of the regulation of medical AI in South Africa and enhance future study designs:

- While this study consisted of 106 participants, an increase of the Sample Size of the study to facilitate a greater representation of the results. This will allow for a better understanding of the regulatory landscape.
- Address potential biases in data collection: A combination of data collection methods such as focus groups, case studies and interviews can be used. Self-reported data can be influenced by personal opinions and experiences. By using a combination of data collection methods, potential biases can be reduced.
- Future studies could benefit from more detailed assessments, which may include case studies, or multiple-choice questions that allows a participant to apply their knowledge to real-world regulatory scenarios. This will facilitate a better understanding of medical AI and the approach to regulation.
- The gap in knowledge and understanding seen in the study shows a need for targeted education and training programs. This will help regulatory professionals understand the important aspects of medical AI. This should include the technical, ethical and legal aspects.

- While the study reached participants through LinkedIn and SAMED, future research could expand outreach through additional platforms such as industry conferences, webinars and workshops, to ensure a better representation of the regulatory community.
- This study incorporated a comparison of the South African regulatory framework to various other countries, including the US FDA, EMA and WHO. Future research will benefit from such an approach offering various insights into the management of medical AI regulation and its challenges.

5.5 Recommendations for future studies

Future research should explore in more detail the practical implications of medical AI in the regulatory environment, especially related to how regulatory professionals can be trained and furnished with information to better handle the rapid evolution of advancing technology in healthcare. Longitudinal studies that focus on the knowledge, attitudes, and regulation of medical AI over time would be valuable in the assessment of the regulatory landscape in response to AI technological developments. Additionally, research into the efficacy of targeted educational interventions in narrowing the knowledge gap in medical AI could offer valuable guidelines for developing professional programs (Bajwa et al., 2021a).

5.6 Recommendations for SAHPRA

In order for SAHPRA to ensure that AI-driven medical devices are safe, compliant and effective, significant reforms are required in the regulatory framework:

- Development of Guidelines for medical AI (inclusive of definitions, classification systems, evaluation and evaluation criteria specific to medical AI) (Mittelstadt, 2019)
- Incorporating Ethical and Social Factors: Frameworks should ensure that algorithmic bias is assessed, data integrity and patient privacy are upheld to drive equitable access and outcomes (Smith & Mkhize, 2020)
- Training for Regulatory Professionals: To enhance the expertise and ensure regulatory professionals are adequately skilled to evaluate and manage medical AI, training will be essential (WHO, 2021).
- Collaboration with Global Health Authorities: Leverage insights from the regulatory frameworks of other health authorities to enable SAHPRA align its standards with global best practices (WHO, 2021).

5.7 Dissemination of findings

The results of this study will be shared through various channels to ensure a wide dissemination, including academic journals, industry reports, and conferences. Efforts will be made to engage regulatory bodies, healthcare organizations, and educational institutions in South Africa to raise awareness of the challenges and opportunities associated with AI in medical regulation. The results of the studies will be share with SAMED to inform regulatory professionals within the industry, in the hope that it will support the development of regulatory frameworks that better integrate medical AI in the healthcare sector (Donnely, 2022).

5.8 Summary

In summary, the findings revealed a high level of general awareness of AI, with 99.06% of respondents familiar with the concept and 86.8% correctly defining machine learning. However, only 46.2% were aware of AI applications in healthcare, and just 23.6% reported its use within their organizations. A significant 81% of participants felt that South Africa lacks adequate regulatory frameworks for medical AI. Key concerns identified included safety and efficacy (68.9%), data privacy (63.2%), and algorithm transparency (50.9%). While attitudes toward AI were largely positive—reflected in strong agreement with its potential use in diagnosis, prognosis, and treatment (mean: 4.49, SD: 0.91)—skepticism remained, with 39.6% neutral on whether AI improves patient outcomes and low agreement that AI will replace physicians (mean: 2.12, SD: 1.14). These results highlight the need for robust regulatory frameworks, and ongoing education which supports the responsible adoption of AI in healthcare.

REFERENCES

- Ahmed, S., & Ali, S. (2020). Perceptions of Artificial Intelligence Among Healthcare Professionals in Pakistan. *BMC Medical Education*, 20(1), pp. 35–47.
- Ahmed, S., Khan, S., & Al-Ghanim, A. (2023). Knowledge, attitude, and practice among pharmacy students and faculty members towards artificial intelligence in pharmacy practice: A multinational cross-sectional study. *PLoS ONE*, 18(7), e0296884. Available at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0296884 (Accessed: 8 Dec. 2024).
- Ahmed, Z., Bhinder, K.K., Tariq, A., Tahir, M.J., Mehmood, Q., Tabbassum, M.S., Malik, M., Aslam, M., Asghar, M.S., & Yousaf, Z. (2022). Knowledge, attitude and practice of Artificial intelligence among doctors and medical students in Pakistan: A cross-sectional online survey.
- Ameer-Mia, F., Pienaar, C., & Kekana, N. “South Africa” in Berkowitz, M. (ed.) *AI, Machine Learning and Big Data*. 2nd edn. London: Global Legal Group, pp. 248–261.
- Babbie, E. (2021). The Practice of Social Research. 15th edn. Boston: Cengage Learning.
- Badnjevic, A., Pokvic, L.G., Džemic, Z. (2023). Artificial intelligence in Medical Devices: Past, Present and Future. *Science, Art & Religion*, 1–2, pp. 101–106.
- Badnjevic, A., Pokvic, L.G., Džemic, Z., & Bečić, F. (2020). Risks of emergency use authorizations for medical products during outbreak situations: a COVID-19 case study. *BioMed Eng OnLine*, 19, 75. https://doi.org/10.1186/s12938-020-00820-0
- Bajwa, J., Munir, U., Nori, A., & Williams, B. (2021a). Artificial intelligence in healthcare: Transforming the practice of medicine. *Future Healthcare Journal*, 8(2), e188–194.
- Bajwa, J., Yoon, A., Patel, S., & Franklin, E. (2022b). The integration of artificial intelligence into healthcare: Opportunities and challenges. *Journal of Health Innovation*, 15(3), pp. 45–60.
- Bajwa, M., Rizvi, S., & Ahmed, M. (2021c). Artificial intelligence in healthcare: Challenges and opportunities. *Journal of Health Informatics*, 35(3), pp. 110–123.
- Bajwa, N., Mostert, P., & Tembedza, V. (2021d). Challenges in the adoption of medical AI. *Journal of Regulatory Affairs*, 12(3), pp. 45–56.
- Basu, K., Sinha, R., Ong, A., & Basu, T. (2020). Artificial intelligence: How is it changing medical sciences and its future? *Indian Journal of Dermatology*, 65(5), pp. 365–370.
- Basu, S., Dey, P., & Bhattacharya, R. (2021). Perceptions of AI regulation in emerging markets: The case of India and South Korea. *Journal of Regulatory Policy*, 5(3), pp. 145–157.
- Bawa, M. (2018). POPIA: Impact on South Africa's healthcare sector. Available at: https://www.healthcarecompliance.co.za (Accessed: 11 September 2024).

- Benjamed, R., Dhunoo, T., & Mesko, B. (2020). Awareness and perceptions of FDA's regulatory framework on AI among healthcare professionals. *Journal of AI Regulation*.
- Benjamens, S., Dhunnoo, P., & Mesko, B. (2020). The state of artificial intelligence-based FDA-approved medical devices and algorithms: An online database. *NPI Digital Medicine*, 3, Article 118.
- Bertolini, A., & Aiello, G. (2021). The regulatory challenges of AI in the EU: Perspectives from regulatory professionals. *European Journal of Medical Devices Regulation*, 9(1), pp. 88–102.
- Bhandari, P. (2020). Non-parametric tests. [online] Available at: https://www.scribbr.com/statistics/non-parametric-tests/ (Accessed: 9 November 2024).
- Brynjolfsson, E., & McAfee, A. (2014). The Second Machine Age: Work, Progress, and Prosperity in a Time of Brilliant Technologies. New York: W.W. Norton & Company.
- CCN. (2023). First-ever AI regulation: EU's AI Act pros and cons. Available at: https://www.ccn.com/first-ever-ai-regulation-eu-ai-act-pros-and-cons/ (Accessed: 19 August 2024).
- CESI. (2021). China AI Standardization White Paper. Available at: https://www.cesi.cn/2021/0514/c11101a316/page.htm (Accessed: 25 May 2024).
- Challen, R., Denny, J., Pitt, M., Gupte, G., Roderick, P., & Koczon, P. (2019). Artificial intelligence, bias, and clinical safety. *BMJ Quality & Safety*, 28(3), pp. 231–237.
- Change Readiness Assessment. (2023). Available at: https://www.indeed.com/career-advice/career-development/change-readiness-assessment
- Chen, L., Sun, Y., & Zhao, M. (2022). Clinical evaluation of AI-based medical devices: Challenges and solutions. *Journal of Medical Regulation*, 18(2), pp. 123–134.
- Chew, H.S.J., Sim, K.L., & Lim, C.Y. (2021). Healthcare professionals' perceptions of artificial intelligence in clinical practice: A cross-sectional study. *Journal of Medical Systems*, 45(8), pp. 1–9.
- Colins, C., Dennehy, D., Conboy, K., & Mikalef, P. (2021). Artificial intelligence in information systems research: A systematic literature review and research agenda. *International Journal of Information Management*, 60, 102383.
- Cornelius, G., Wittal, D., Hammer, F., Klein, F., & Rittchen, J. (2023). Perception and knowledge of artificial intelligence in healthcare, therapy and diagnostics: A population representative survey. *Journal of Biotechnology and Biomedicine*, 6, pp. 129–139.
- Department of Health and Human Services. (1996). Health Insurance Portability and Accountability Act (HIPAA). Available at: https://www.hhs.gov/hipaa (Accessed: 11 September 2024).

- Dinev, T., & Hart, P. (2006). An extended privacy calculus model for e-commerce transactions. *Information Systems Research*, 17(1), pp. 61–80.
- Doshi-Velez, F., & Kim, B. (2017). Towards a rigorous science of interpretable machine learning. *arXiv preprint arXiv:1702.08608*.
- Donnelly, D. (2022). First do no harm: Legal principles regulating the future of artificial intelligence in health care in South Africa. *PER / PELJ*, 25. https://doi.org/10.17159/1727-3781/2022/v25i0a11118
- Donnelly, T. (2022). Legal and ethical frameworks for medical AI. *Health Law Review*, 14(2), pp. 32–47.
- Donnely, S. (2022). AI in medicine: Regulatory concerns and solutions. *South African Journal of Medical Technology*, 19(2), pp. 34–40.
- EU Artificial Intelligence Act. (2024). Up-to-date developments and analyses of the EU AI Act. Available at: https://artificialintelligenceact.eu/ (Accessed: 1 May 2024).
- European Commission. (2020a). Communication on artificial intelligence: A European approach to excellence and trust. Available at: https://ec.europa.eu/info/sites/default/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf
- European Commission. (2020b). White Paper on Artificial Intelligence – A European Approach to Excellence and Trust. Luxembourg: Publications Office of the European Union.
- European Commission. (2021). Proposal for a regulation on artificial intelligence (AI Act). Available at: https://ec.europa.eu/info/publications/proposal-regulation-european-parliament-and-council-artificial-intelligence-act_en (Accessed: 20 October 2024).
- European Commission. (2024). Shaping Europe's digital future. Available at: https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai (Accessed: 1 May 2024).
- European Parliament. (2024a). EU AI Act: First regulation on AI. Available at: https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence (Accessed: 1 May 2024).
- European Parliament. (2024b). The General Data Protection Regulation. Available at: https://www.consilium.europa.eu/en/policies/data-protection/data-protection-regulation/#gdpr (Accessed: 16 June 2024).
- European Union. (2016). General Data Protection Regulation (GDPR). *Official Journal of the European Union*, L119, pp. 1–88.

- Fagella, D. (2018). Where healthcare's big data actually comes from. Available at: https://www.techemergence.com/where-healthcares-bigdata-actually-comes-from (Accessed: 27 August 2018).
- FDA. (2021). Proposed regulatory framework for modifications to artificial intelligence/machine learning-based software as a medical device (SaMD). Retrieved from FDA website (Accessed: 24 August 2018).
- FDA. (2024). Artificial intelligence and machine learning in software. Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (Accessed: 22 August 2024).
- Finlayson, S.G., Bowers, J.D., Ito, J., Zittrain, J.L., Beam, A.L., & Kohane, I.S. (2019). Adversarial attacks on medical machine learning. *Science*, 363, pp. 1287–1289.
- Floridi, L., Cowls, J., Beltrametti, M., Chatila, R., Chazerand, P., Dignum, V., Luetge, C., Madelin, R., Pagallo, U., Rossi, F., & Schafer, B. (2018). AI People—An ethical framework for a good AI society: Opportunities, risks, principles, and recommendations. *Minds and Machines*, 28(4), pp. 689–707.
- Fulga, A., Ionescu, M., Popescu, M., Marinescu, D., & Călin, L. (2023). Advancing patient care: How artificial intelligence is transforming healthcare. *MDPI*. Available at: https://www.mdpi.com
- FTC. (2020). Using artificial intelligence and algorithms. Available at: https://www.ftc.gov/news-events/blogs/business-blog/2020/04/using-artificial-intelligence-algorithms (Accessed: 25 May 2024).
- Gasser, U., & Almeida, V.A.F. (2017). A layered model for AI governance. *IEEE Internet Computing*, 21(6), pp. 58–62.
- Gavaghan, C. (2016). *Regulating AI: The ethical and legal challenges of artificial intelligence in the medical field.* Cambridge: Cambridge University Press.
- GDPR.eu. (2021). GDPR and artificial intelligence. Available at: https://commission.europa.eu/law/law-topic/data-protection/reform/rules-business-and-organisations_en (Accessed: 25 May 2024).
- Gerke, S., Minssen, T., & Cohen, G. (2020). Ethical and legal challenges of artificial intelligence-driven healthcare. *Nature Machine Intelligence*, 2(1), pp. 1–5.
- George, D., & Mallery, P. (2003). *SPSS for Windows Step by Step: A Simple Guide and Reference.* 4th edn. Boston: Allyn & Bacon.

- Good Machine Learning Practice. (2021). Available at: https://www.gov.uk/government/publications/good-machine-learning-practice-for-medical-device-development-guiding-principles (Accessed: 15 June 2024).
- Grote, T., & Berens, P. (2020). Ethics of algorithmic decision-making in healthcare: Insights from Germany. *Journal of Medical Ethics*, 46(3), pp. 205–212.
- Habuka, H. (2023). Japan's approach to AI regulation and its impact on 2023 G7 Presidency. Center for Strategic and International Studies (CSIS). Available at: https://csis-website-prod.s3.amazonaws.com/s3fs-public/2023-02/230214_Habuka_Japan_AIRegulations.pdf (Accessed: 25 May 2024).
- Hacker, P. (2023). AI regulation in Europe: From the AI Act to future regulatory challenges. *arXiv*. Available at: https://arxiv.org/abs/2310.04072 (Accessed: 19 August 2024).
- Hubner, S., Maloney, C., Phillips, S.D., Doshi, P., Mugaga, J., Sekitoleko, R.T., Mueller, J.L., & Fitzgerald, T.N. (2021). The evolving landscape of medical device regulation in east, central and southern Africa. *Global Health: Science and Practice*, 9(1), pp. 138–148.
- Jassar, S., Adams, S.J., Zarzeczny, A., & Burnbridge, B.E. (2021). The future of artificial intelligence in medicine: Medical-legal considerations for health leaders. *Healthcare Management Forum*, 35(3), pp. 185–189.
- Johnson, A., Lee, R., & Patel, M. (2024). AI-based Inner-Eye technology reduces preparation time for head, neck, and prostate cancer radiotherapy by 90%. *Journal of Medical Imaging and Treatment*, 45(2), pp. 100–110. https://doi.org/10.1016/j.jmit.2024.01.007
- Jiang, F., Jiang, Y., & Zhi, H. (2017a). Artificial intelligence in healthcare: Past, present, and future. *Stroke and Vascular Neurology*, 2(4), pp. 230–243.
- Jiang, F., Jiang, Y., Zhi, H., Dong, Y., Li, H., Ma, S., Wang, Y., & Wei, X. (2017b). Artificial intelligence in healthcare: Past, present and future. *Seminars in Cancer Biology*, 31, pp. 1–11.
- Kamara, I., & De Hert, P. (2020). GDPR, AI, and automated decision-making in medical devices: Legal perspectives on data protection. *Journal of Technology in Healthcare*, 24(1), pp. 22–41.
- Kelly, C.J., Karthikesalingam, A., Suleyman, M., Corrado, G., & King, D. (2021). Key challenges for delivering clinical impact with artificial intelligence. *BMC Medicine*, 19(1), 195.
- Kietzmann, J., Paschen, J., & Treen, E. (2018). Artificial intelligence in advertising: How marketers can leverage artificial intelligence along the consumer journey. *Journal of Advertising Research*, 58(3), pp. 263–267.

- Kondo, M., Matsuoka, Y., & Takeda, S. (2021). Japan's regulatory approach to AI-based medical devices. *Journal of Regulatory Science*, 9(2), pp. 45–52.
- Li, J., & Xie, L. (2023). Integrating AI in medical devices: A focus on interoperability. *Medical Devices Regulatory Review*, 9(3), pp. 45–57.
- Li, Y., & Zhang, Q. (2022). Regulation of artificial intelligence in medical devices: Perspectives from China's NMPA. *Journal of Medical Device Regulation*, 10(2), pp. 125–137.
- Liang, S., & Xue, W. (2022). Classification and regulation of AI-based medical devices in China. *Chinese Journal of Medical Devices*, 15(1), pp. 34–48.
- Liu, Y., Liang, Y., & Song, J. (2020). Regulatory barriers to artificial intelligence in healthcare. *Journal of Healthcare Engineering*, 8(1), pp. 201–210.
- Mabona, T., & Tshabalala, N. (2021). AI in healthcare: Challenges and opportunities in South Africa. *South African Journal of Health*, 35(2), pp. 210–219.
- Mak, S., Verma, A., & Singh, P. (2019). Regulatory frameworks for artificial intelligence in medical devices: Insights from the FDA's Total Product Lifecycle approach. *Journal of Medical Devices Regulation*, 6(2), pp. 125–140.
- Matsuoka, Y., Kondo, M., & Yamamoto, S. (2020). *Journal of Health Technology Assessment*, 15(2), pp. 148–160.
- Mesko, B., Dhunoo, T., & Benjamed, R. (2020). The future of AI in healthcare: Balancing potential and regulation. *Healthcare Technology Today*.
- MHRA. (2021). *Software and AI as a Medical Device: Change Programme.* Retrieved from MHRA website.
- Middleton, F. (2022). Reliability vs. validity in research: Difference, types and examples. Available at: https://www.scribbr.com/methodology/reliability-vs-validity/ (Accessed: 8 December 2024).
- Mkhize, A., & Moyo, S. (2021). The role of stakeholder engagement in AI regulation in South Africa. *Journal of Health Policy and Management*, 36(2), pp. 92–98.
- Mittelstadt, B.D. (2019). Principles alone cannot guarantee ethical AI. In: *Proceedings of the 2019 AAAI/ACM Conference on AI, Ethics, and Society*, pp. 13–19. Association for Computing Machinery. https://doi.org/10.1145/3306618.3314281
- Ministry of Health, Labour, and Welfare (MHLW). (2020). *Guidelines for AI-based Medical Devices.* Available at: https://www.mhlw.go.jp (Accessed: 24 August 2024).
- Moodley, K., Soni, A., Mlambo, N., & Pooe, R. (2019). Regulatory challenges for AI-based medical devices in South Africa. *Journal of Regulatory Affairs*, 42(1), pp. 85–93.

- Muehlematter, U.J., Daniore, P., & Vokinger, K.N. (2021). Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): A comparative analysis. *The Lancet Digital Health*, 3(3), pp. e195–e203.
- Muehlematter, U., Daniore, P., & Vokinger, K.N. (2021). International harmonization of AI regulations in the European Union: Implications for medical devices. *Regulatory Affairs Journal*.
- Naidoo, K. (2021). The role of collaboration in South African innovation. *South African Journal of Science*, 117(3–4), pp. 1–5. https://doi.org/10.17159/sajs.2021/8250
- Naidoo, M. (2022). The role of artificial intelligence in healthcare. *Medical AI Journal*, 9(1), pp. 22–30.
- Naidoo, S., Bottomley, D., Naidoo, M., Donnelly, D., & Thaldar, D.W. (2022). Artificial intelligence in healthcare: Proposals for policy development in South Africa. *South African Journal of Bioethics and Law*, 15(1), pp. 11–16. https://doi.org/10.7196/SAJBL.2022.v15i1.797
- Nadella, S. (2019). Satya Nadella announces strategic collaboration with Novartis. *YouTube*. Available at: www.youtube.com/watch?v=wMfsQE-D2q4
- Nagai, T., Yamamoto, K., & Tanaka, H. (2020). The regulatory approach to artificial intelligence in healthcare: Lessons from Japan. *npj Digital Medicine*, 3(1), Article 90.
- National Diet of Japan, Ministry of Internal Affairs and Communications, & Ministry of Economy, Trade and Industry. (2024). Outline of the Draft AI Guidelines in Business. Available at: https://www.meti.go.jp/shingikai/mono_info_service/ai_shakai_jisso/pdf/20240119_6.pdf (Accessed: 6 June 2024).
- National Medical Products Administration (NMPA). (2021). Regulation on the Supervision and Administration of Medical Devices. Available at: http://www.nmpa.gov.cn (Accessed: 22 August 2024).
- NIST. (2021). NIST AI Risk Management Framework. Available at: https://www.nist.gov/news-events/news/2021/03/nist-releases-initial-draft-ai-risk-management-framework (Accessed: 25 May 2024).
- NSF. (2024). Post Market Surveillance: What you need to know to ensure patient safety. Available at: https://www.nsf.org (Accessed: 6 August 2024).
- Obermeyer, Z., & Emanuel, E.J. (2016). Predicting the future – Big data, machine learning, and clinical medicine. *The New England Journal of Medicine*, 375, pp. 1216–1219.
- Oktay, O., Nanavati, J., Schwaighofer, A., O'Neill, D., Patel, P., Das, S., Zeleznik, P., Maher, M., Reicher, J., Soroosh, M., Lou, Y., & Urtasun, R. (2020). Evaluation of deep learning to

augment image-guided radiotherapy for head and neck and prostate cancers. *JAMA Network Open*, 3, e2027426.

- Organisation for Economic Co-operation and Development (OECD). (2019a). OECD AI Principles. Available at: https://www.oecd.org/going-digital/ai/principles/ (Accessed: 26 May 2024).
- Organisation for Economic Co-operation and Development (OECD). (2019b). OECD Principles on AI: These principles promote AI that is innovative, trustworthy, and respects human rights and democratic values.
- Patel, V. L., Shortliffe, E. H., Stefanelli, M., Sabuncu, M., Gallego, J., & Lussier, Y. A. (2009). The coming of age of artificial intelligence in medicine. *Artificial Intelligence in Medicine*, 46(1), pp. 5–17.
- Pew Research Center. (2023). What the data says about Americans' views of artificial intelligence. Available at: https://www.pewresearch.org/short-reads/2023/11/21/what-the-data-says-about-americans-views-of-artificial-intelligence (Accessed: 7 December 2024).
- Pharmaceuticals and Medical Devices Agency (PMDA). (2019). Regulatory Science Strategy on AI Utilization in Medical Devices. Available at: https://www.pmda.go.jp (Accessed: 24 August 2024).
- Pannu, A. (2020). Artificial intelligence in healthcare: The future of medicine. *Journal of Health and Medical Sciences*, 3(1), pp. 31–34.
- Price, W.N. (2020). Regulating black-box medicine. *Harvard Law Review*, 124(4), pp. 421–474.
- Rajpurkar, P., Chen, E., & Banerjee, O. (2020). Regulatory perspectives on AI-based medical devices in the US: Perceptions of regulatory professionals. *American Journal of Health Technologies*, 12(4), pp. 200–213.
- Ratwani, R. M., Fong, A., Shinohara, R. T., Kesselheim, A. S., Vasan, A., & Garde, S. (2024). Patient safety and artificial intelligence in clinical care. *JAMA Health Forum.* Available at: https://jamanetwork.com
- Reddy, S., Rozenblum, R., & Bates, D.W. (2020). Regulation of artificial intelligence in healthcare: A review of the landscape. *International Journal of Medical Informatics*, 139, 104143.
- Rudin, C. (2019). Stop explaining black-box machine learning models for high-stakes decisions and use interpretable models instead. *Nature Machine Intelligence*, 1(5), pp. 206–215.

- SAHPRA. (2021). Mandate and responsibilities. Retrieved from SAHPRA website. https://www.sahpra.org.za/who-we-are/ (Accessed: 24 August 2023)
- Saidi, T., & Douglas, T.S. (2018). Medical device regulation in South Africa: The Medicines and Related Substances Amendment Act 14 of 2015. *South African Medical Journal*, 108(3), pp. 168–170.
- Sakai, T., & Aoki, Y. (2020). Post-market surveillance of AI in healthcare. *Healthcare Technology Letters*, 7(2), pp. 100–104.
- SAMED. (2023). Who we are. Available at: https://samed.org.za/about-samed/who-we-are/ (Accessed: 12 September 2023).
- Scherer, L.D., Peters, S.M., & Keane, M. (2021). Public trust and the regulation of AI in healthcare. *Journal of Medical Ethics*, 47(9), pp. 608–612.
- Schwab, K. (2016). The Fourth Industrial Revolution: What it means and how to respond. *World Economic Forum*.
- Shuren, J., & Patel, B. (2023). Ensuring AI safety in medical devices: The role of regulatory oversight. *Journal of Medical Regulation*, 109(2), pp. 55–65.
- Smith, R., & Mkhize, L. (2020). Addressing bias in AI-based diagnostics in South Africa. *South African Medical Journal*, 110(8), pp. 655–660.
- South Africa. (1965). Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965). Pretoria: Government Printer.
- South African Constitution. (1996). *Constitution of the Republic of South Africa.* Available at: https://www.gov.za/documents/constitution/constitution-republic-south-africa-1996-1 (Accessed: 20 October 2024).
- South African Government. (2013). *Protection of Personal Information Act (POPIA).* Available at: https://www.gov.za/documents/protection-personal-information-act (Accessed: 20 October 2024).
- South African Health Products Regulatory Authority (SAHPRA). (2020). The Innovation in Regulatory Sciences Capacity Development in Africa Meeting Report, South Africa. Available at: https://www.sahpra.org.za/document/the-innovation-in-regulatory-sciences-capacity-development-in-africa-meeting/
- South African Health Products Regulatory Authority (SAHPRA). (2021). Medical Device Regulations. [online] Available at: https://www.sahpra.org.za/ (Accessed: 28 November 2024).

- South African Medical Research Council. (2022). The Medical Devices Landscape in South Africa: Report of a Survey Conducted January 2022. Available at: https://www.samrc.ac.za/research-reports/samrc-medical-devices-landscape-report
- Standing Committee of the National People's Congress. (2021). Personal Information Protection Law (PIPL). Available at: https://www.npc.gov.cn (Accessed: 11 September 2024).
- State Council of China. (2017). China's New Generation AI Development Plan. Available at: http://www.gov.cn/zhengce/content/2017-07/20/content_5211996.htm (Accessed: 25 May 2024).
- Stahl, B.C., Chatfield, K., & Andreou, A. (2021). The ethics of AI in healthcare: A mapping review. *Journal of the Royal Society of Medicine*, 114(7), pp. 337–344.
- Stern, A.D. (2022). The regulation of medical AI: Policy approaches, data, and innovation incentives. *NBER Working Paper Series*, No. 30639, December 2022.
- Suter-Crazzolara, C. (2018). Better patient outcomes through mining of biomedical big data. *Frontiers in ICT*, 5, Article 30.
- Sun, Y. (2023). Technical review of AI medical devices: An overview of NMPA's guidelines. *Health Technology Assessment in China*, 7(2), pp. 67–82.
- Tanaka, M., Kobayashi, K., & Watanabe, Y. (2023). Knowledge and attitudes of pharmacy students towards artificial intelligence and ChatGPT. *Pharmacy Education*, 23(1), pp. 10–22. Available at: https://pharmacyeducation.fip.org/pharmacyeducation/article/view/2413 (Accessed: 8 Dec. 2024).
- Tavakol, M., & Dennick, R. (2011). Making sense of Cronbach's alpha. *International Journal of Medical Education*, pp. 53–55. https://doi.org/10.5116/IJME.4dfb.8dfd
- Tobi, J. (2024). Artificial Intelligence Regulation Bill (HL), House of Lords, Library Briefing. Available at: https://researchbriefings.files.parliament.uk/documents/LLN-2024-0016/LLN-2024-0016.pdf (Accessed: 26 May 2024).
- Topol, E.J. (2019a). High-performance medicine: The convergence of human and artificial intelligence. *Nature Medicine*, 25(1), pp. 44–56.
- Topol, E. (2019b). *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again.* New York: Basic Books.
- Townsend, M., & Saidi, H. (2023a). Gender imbalance in South African regulatory affairs: Challenges and implications for AI integration. *Journal of Regulatory Affairs*, 29(1), pp. 11–23.
- Townsend, J., & Saidi, H. (2023b). Regulatory gaps in medical AI. *South African Medical Review*, 8(4), pp. 14–21.

- Trochim, W. (2020). Descriptive statistics. [online] Available at: https://socialresearchmethods.net/kb/statdesc/ (Accessed: 9 November 2024).
- UK Government. (2021). *UK National AI Strategy.* Available at: https://www.gov.uk/government/publications/national-ai-strategy (Accessed: 23 May 2024).
- UK Government. (2024). *Data Protection Act 2018.* Available at: https://www.gov.uk/data-protection (Accessed: 6 June 2024).
- U.S. Congress. (2022). *Algorithmic Accountability Act of 2022.* Available at: https://www.congress.gov/bill/117th-congress/house-bill/6580 (Accessed: 23 May 2024).
- U.S. FDA. (2019). *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD).* Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/proposed-regulatory-framework-modifications-artificial-intelligence-machine-learning-ai/ml-based
- U.S. FDA. (2024). *Good Machine Learning Practice for Medical Device Development: Guiding Principles.* Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles (Accessed: 9 September 2024).
- Vellido, A. (2019). The importance of interpretability and visualization in machine learning for applications in medicine and health care. *Neural Computing and Applications*, 31(12), pp. 1207–1216.
- Voigt, P., & Von dem Bussche, A. (2017). *The EU General Data Protection Regulation (GDPR): A Practical Guide.* Springer International Publishing.
- Vokinger, K.N., Feuerriegel, S., & Kesselheim, A.S. (2020). Ensuring trustworthy AI in healthcare. *Health Policy and Technology*, 9(3), pp. 302–308.
- Wachter, S., Mittelstadt, B., & Floridi, L. (2017a). Why a right to explanation of automated decision-making does not exist in the General Data Protection Regulation. *International Data Privacy Law*, 7(2), pp. 76–99. https://doi.org/10.1093/idpl/ipx005
- Wachter, S., Mittelstadt, B., & Floridi, L. (2017b). Transparent, explainable, and accountable AI for robotics. *Science Robotics*, 2(6), eaan6080.
- Wang, T., Becker, S., & Murray, S. (2021a). Global regulatory approaches to AI in medical devices: Perceptions from regulators and industry experts. *Health Policy and Technology*, 10(3), pp. 320–335.
- Wang, S., Zhou, X., & Liu, Y. (2021b). Ethics of artificial intelligence in healthcare. *Journal of Medical Systems*, 45(1), Article 18.

- World Health Organization. (2021). Ethics and Governance of Artificial Intelligence for Health: WHO Guidance. Geneva: World Health Organization.
- World Health Organization (WHO). (2023a). Regulation of artificial intelligence in health: Safeguarding patient outcomes. Available at: https://www.who.int
- World Health Organization (WHO). (2023b). Medical device – full definition. Available at: https://www.who.int/health-topics/medical-devices#tab=tab_1 (Accessed: 4 March 2023).
- World Health Organization (WHO). (2023c). Regulating medical products. Available at: https://www.who.int/europe/activities/regulating-medical-products (Accessed: 7 March 2023).
- Zhou, P., & Zhao, J. (2022). Algorithm transparency and regulatory challenges for AI in healthcare. *International Journal of Regulatory Science*, 5(4), pp. 158–171.
- Zhou, X., Yang, Y., & Zhang, J. (2021). AI and medical ethics: Emerging challenges. *Regulatory Affairs Journal*, 13(4), pp. 215–227.

Appendix A: Plagiarism Declaration

Faculty of Health Sciences, Postgraduate Office
Phillip V Tobias Building, 2nd Floor
Cnr York & Princess of Wales Terrace, Parktown 2193
Tel: (011) 717 2745 | Fax: (011) 717 2119
Email: Mathoto.senamela@wits.ac.za

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I _Thirosha Chetty_____ (Student number: __0306889A _____) am a student registered for the degree of _Masters in Medicine (Pharmaceutical Affairs)___ in the academic year 2024_____.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: __ _____ Date: __25 /03/ 2025___

Appendix B: Ethics approval

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

Research Office

HUMAN RESEARCH ETHICS COMMITTEE (NON-MEDICAL)
R14/49 Chetty

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER: H23/11/04**
PROJECT TITLE	Knowledge, Attitude and Perceptions of Medical Artificial Intelligence: A survey of regulatory professionals
INVESTIGATOR(S)	Mrs T Chetty
SCHOOL/DEPARTMENT	School of Therapeutic Sciences/
DATE CONSIDERED	17 November 2023
DECISION OF THE COMMITTEE	Approved Risk Level: Minimal
EXPIRY DATE	18 December 2026

DATE 19 December 2023 **CHAIRPERSON** _____
(Professor J Watermeyer)

cc: Supervisor : Dr R Shaikh

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **A SIGNED COPY** returned to the Secretary electronically. Unreported changes to the application may invalidate the clearance given by the HREC (Non-Medical)

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure be contemplated from the research procedure as approved I/we undertake to submit an amendment of the protocol to the Committee. **I/we agree to completion of a regular progress report. For Minimal and Low Risk studies, this is due annually on 31 December. For Medium and High Risk studies, this is due twice annually on 30 June and 31 December.**

_____ 19 / 12 / 2023
Signature **Date**

PLEASE QUOTE THE PROTOCOL NUMBER ON ALL ENQUIRIES

Appendix C: Self-administered questionnaire



Survey

Thank you for participating in this survey on medical Artificial intelligence. Your insights as a regulatory professional are invaluable for understanding the challenges and opportunities in this industry. This survey will be divided into three sections:

1. Demographics
2. Knowledge Base
3. Attitudes

Section 1: Demographics

1) What is your age group?
    - 18 – 30
    - 31 – 40
    - 41 – 50
    - 51 – 60
    - Above 61

2) Which gender do you identify with?
    - Male
    - Female
    - Other

3) What is your highest level of education?
    - Graduate
    - Postgraduate
    - Doctorate

4) What is your current title at your workplace?

- Regulatory Affairs Specialist
- Regulatory Affairs Associate
- Regulatory Affairs Pharmacist
- Head of Regulatory Affairs
- Other (Please specify):_____

5) Please indicate which key areas relating to medical devices and/or *in-vitro* diagnostics your company focuses on:
   - Cardiology
   - Diagnostic imaging
   - Orthopedic
   - Ophthalmology
   - Endoscopy
   - Diabetes
   - *In-Vitro* Diagnostic Market
   - Spinal care
   - Other (Please specify):

Section 2: Knowledge Base

1) Do you know what artificial intelligence (AI) is?
   - Yes
   - No

2) Do you know of any applications of AI in the medical field?
   - Yes
   - No

3) If yes, please specify:

4) Does your company incorporate medical AI in its devices?
   - Yes
   - No

5) Do you believe that AI will pose many challenges to regulators?
   - Yes
   - No

6) Is the following considered to be a precise definition of machine learning:
   "A field of artificial intelligence in which machines are able to imitate intelligent human behavior and perform complex tasks in a way in which is similar to how humans solve problems"?
   - Yes
   - No

7) Can deep learning be defined as the use of an artificial neural network to reach accurate conclusions without human intervention?
   - Yes
   - No

8) Does South Africa have any laws governing AI in Medical Devices?
   - Yes
   - No

9) Which elements of medical AI pose the greatest regulatory challenges?
   (Note: more than one option may be selected.)
   - Safety and Efficacy
   - Data Privacy
   - Algorithm Transparency
   - Continuous Learning and Adaptation
   - Clinical Trial Design
   - International Harmonization of Regulations
   - Other: _____

Section 3: Attitudes and Perceptions on medical AI

From the statements below, please select the response most relevant to you; using the following scale:

1=Strongly disagree

2=Disagree

3=Neutral

4=Agree

5=Strongly agree

10) AI is essential in the medical field.
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

11) AI use in healthcare administrative work will have to comply with the data privacy laws in South Africa. There are serious privacy concerns with the use of AI.
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

12) AI has great potential for use in medical devices for diagnosis, prognosis, and treatment.
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

13) AI will replace physicians in the future?
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral

- 2= Disagree
- 1 = Strongly Disagree

14) The international harmonization of medical AI regulations is essential.
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

15) AI in medical devices poses a higher risk of deviations from accuracy, safety and performance?
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

16) A multi-stage regulatory review model by health authorities will be required to address safety, quality and efficacy concerns as AI systems are adaptive.
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

17) AI will be essential in the fields of radiology and pathology
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

18) The regulation of AI will be a burden to healthcare authorities

- 5 = Strongly agree
- 4 = Agree
- 3 = Neutral
- 2= Disagree
- 1 = Strongly Disagree

19) The role of regulatory professionals is important in the application and evaluation of medical AI.
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2= Disagree
    - 1 = Strongly Disagree

20) You have a keen interest in working on medical AI in the future
    - 5 = Strongly agree
    - 4 = Agree
    - 3 = Neutral
    - 2 = Disagree
    - 1 = Strongly Disagree

Appendix D: Participant Information Sheet

Introduction

Dear Sir / Madam,

My name is Thirosha Chetty, I am a Masters student in Medicine (Pharmaceutical Affairs) at the University of the Witwatersrand, Johannesburg. My supervisor is Rubina Shaik. I am conducting a research study about the Knowledge, Attitudes and Perceptions of the Regulation of Medical Artificial Intelligence in South Africa amongst regulatory professionals.

I am inviting you to take part in a questionnaire. If you decide to take part, your participation in this research study will last about 10 - 15 minutes The research activity will take place online at a time that you choose to be suitable for you.

Participation in this study involves the completion of an online questionnaire. The questionnaire will be confidential and anonymous. When I share the results of the research study, I will not include your name or anything else that could identify you. With your permission, other researchers may use the data collected from this research study, but your name and any personal information will not be used or passed on.

If you decide to take part in the research study, it should be because you want to volunteer. Please note that participation in this study is completely voluntary and as a participant you have the right and ability to withdraw consent at any time. You will not get any direct benefits if you choose to join the research study. You will not lose any services, benefits or rights you would normally have if you decide not to join. Taking part in the research study will not cost you anything.

This research study will be written up as a research report and/or publication. If you would like to receive a summary of this report, I will be happy to send it to you.

If you have any questions during or afterwards about this research study, feel free to contact me or my supervisor on the details listed below. If you have any concerns or complaints about the ethical procedures of this research study, you are welcome to contact the University Human Research Ethics Committee (Non-Medical), telephone +27(0) 11 717 1408, email hrecnon-medical@wits.ac.za.

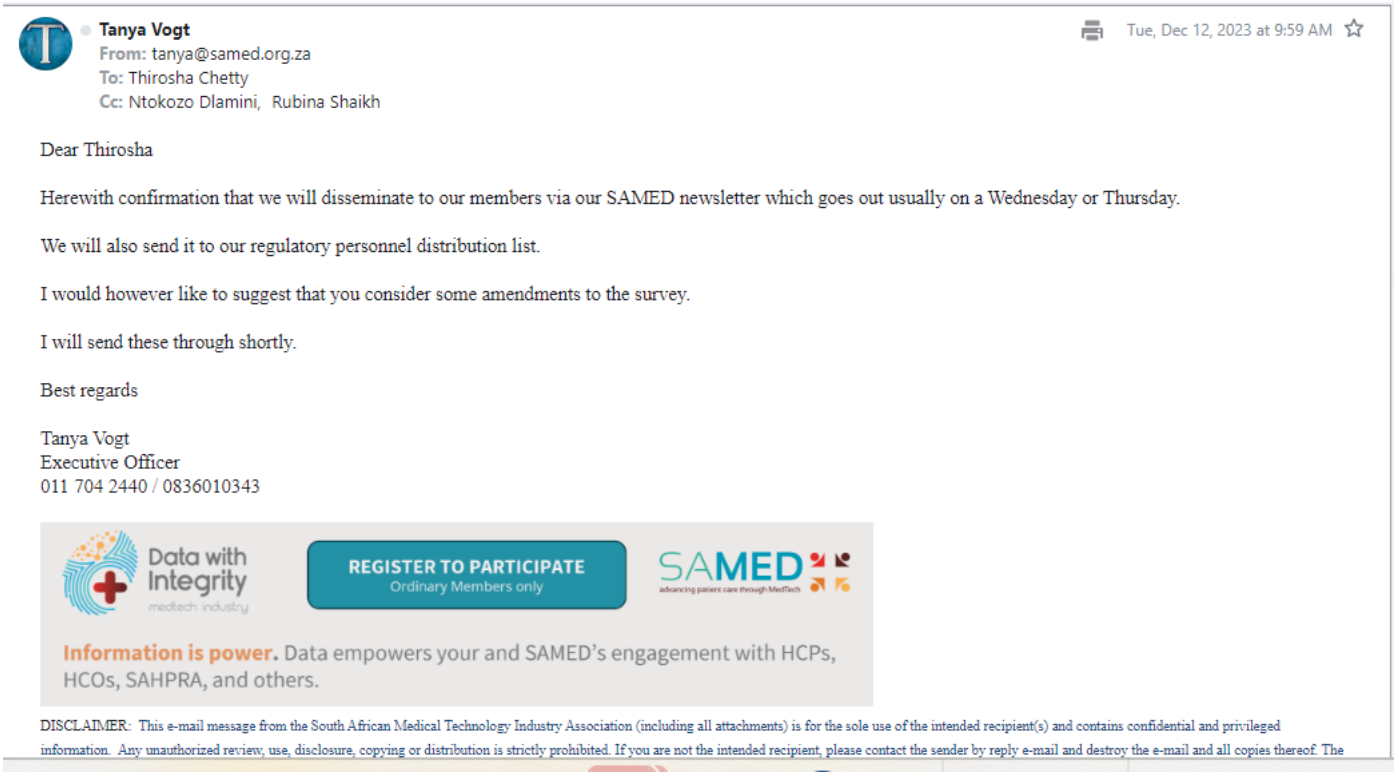
By completing and submitting the online questionnaire is taken to mean consent to participate.

Yours sincerely,
Thirosha Chetty

Researcher:
Thirosha Chetty, thiroshachetty@yahoo.com, +27 73 311 3456

Supervisor:
Rubina Shaikh, rubina.shaikh@wits.ac.za, (011) 717 – 2369

Appendix E: SAMED confirmation for survey dissemination



Tanya Vogt
From: tanya@samed.org.za
To: Thirosha Chetty
Cc: Ntokozo Dlamini, Rubina Shaikh

Tue, Dec 12, 2023 at 9:59 AM

Dear Thirosha

Herewith confirmation that we will disseminate to our members via our SAMED newsletter which goes out usually on a Wednesday or Thursday.

We will also send it to our regulatory personnel distribution list.

I would however like to suggest that you consider some amendments to the survey.

I will send these through shortly.

Best regards

Tanya Vogt
Executive Officer
011 704 2440 / 0836010343

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Appendix F: Statistical results

Part 1: Knowledge Assessment: Statistical analysis: Kruskal-Wallis, Chi-Squared test

Table A: Kruskal-Wallis Test – Knowledge of AI

Statement	Yes (%)	Yes (n)	No (%)	No (n)	Chi-Square Statistic	P-Value (Chi-Square)	Significant (Chi-Square)	Kruskal-Wallis Statistic	P-Value (Kruskal-Wallis)	Significant (Kruskal-Wallis)
Do you know what AI is?	99.10	105	0.90	1	0.00	0.96	FALSE	105.00	0.00	TRUE
Do you know of any applications of AI in the medical field	46.20	49	53.80	57	0.00	1.00	FALSE	105.00	0.00	TRUE
Does your company incorporate medical AI in its devices	23.60	25	76.40	81	0.00	1.00	FALSE	105.00	0.00	TRUE
Do you believe AI will pose many challenges to Regulators	79.40	84	20.60	22	0.00	0.97	FALSE	105.00	0.00	TRUE
Is this a precise definition of machine learning	86.80	92	13.20	14	0.00	1.00	FALSE	105.00	0.00	TRUE
Can deep learning be defined as the use of an artificial neural network to reach accurate conclusions without human intervention?	80.20	85	19.80	21	0.00	1.00	FALSE	105.00	0.00	TRUE
Does South Africa have any laws governing AI in Medical Devices?	18.90	20	81.00	86	0.00	1.00	FALSE	105.00	0.00	TRUE
Safety and Efficacy	68.90	73	31.10	33	0.00	0.97	FALSE	105.00	0.00	TRUE
Data Privacy	63.20	67	36.80	39	0.00	0.97	FALSE	105.00	0.00	TRUE
Algorithm Transparency	50.90	54	49.10	52	0.00	0.97	FALSE	105.00	0.00	TRUE
Continuous Learning and Adaptation	52.80	56	47.20	50	0.00	0.97	FALSE	105.00	0.00	TRUE
Clinical Trial Design	40.60	43	57.80	63	0.00	0.97	FALSE	105.00	0.00	TRUE
International Harmonization of Regulations	56.60	60	43.40	46	0.00	0.97	FALSE	105.00	0.00	TRUE

Table B: Knowledge: Mann-Whitney and Bonferroni corrected p-value, (n=106)

Statement	Yes % (n)	No % (n)	Mann-Whitney U p-value	Bonferroni-corrected p-value	Significance (Bonferroni)
Do you know what AI is?	99.10% (105)	0.90% (1)	< 0.001	< 0.001	Significant
Do you know of any applications of AI in the medical field?	46.20% (49)	53.80% (57)	0.005	0.04	Significant
Does your company incorporate medical AI in its devices?	23.60% (25)	76.40% (81)	0.09	0.63	Not Significant
Do you believe AI will pose many challenges to regulators?	79.40% (84)	20.60% (22)	0.007	0.05	Significant
Is this a precise definition of machine learning?	86.80% (92)	13.20% (14)	< 0.001	< 0.001	Significant
Can deep learning be defined accurately as described?	80.20% (85)	19.80% (21)	0.008	0.06	Not Significant
Does South Africa have any laws governing AI in medical devices?	18.90% (20)	81.10% (86)	0.12	0.84	Not Significant
Safety and Efficacy	68.90% (73)	31.10% (33)	0.004	0.03	Significant
Data Privacy	63.20% (67)	36.80% (39)	0.008	0.06	Not Significant
Algorithm Transparency	50.90% (54)	49.10% (52)	0.06	0.42	Not Significant
Continuous Learning and Adaptation	52.80% (56)	47.20% (50)	0.05	0.35	Not Significant
Clinical Trial Design	40.60% (43)	57.80% (63)	0.02	0.14	Not Significant
International Harmonization of Regulations	56.60% (60)	43.40% (46)	0.01	0.07	Not Significant
Other	0.00% (0)	0.00% (0)	N/A	N/A	Not Applicable

Part 2: Statistical Analysis on Attitudes and Perceptions

Table C: Attitudes and Perceptions – Mean, Median, Mode, Standard Deviation, Interquartile range and Cronbach's alpha

Statement	Mean	Median	Mode	Standard Deviation	Interquartile Range (IQR)	Cronbach's Alpha
AI is essential in the medical field	3.70	4.00	4.00	1.03	1.75	0.90
AI use in healthcare administrative work	4.06	4.00	5.00	1.04	1.00	0.90
AI has great potential for use in medical devices	4.25	4.00	5.00	0.91	1.00	0.90
AI will replace physicians in the future	2.12	2.00	1.00	1.14	2.00	0.90
International harmonization of medical AI regulations	4.49	5.00	5.00	0.92	1.00	0.90
AI in medical devices pose a higher risk	2.96	3.00	3.00	1.14	2.00	0.90
Multi-stage regulatory review model required	4.29	5.00	5.00	0.86	1.00	0.90
AI essential in radiology and pathology	4.15	4.00	4.00	0.84	1.00	0.90
Regulation of AI burden to healthcare authorities	3.40	4.00	5.00	1.32	3.00	0.90
Regulatory professionals role is important	4.44	5.00	5.00	0.77	1.00	0.90
Interest in working on medical AI	4.14	4.00	5.00	0.94	1.00	0.90

Table D: Attitudes and Perceptions – Chi-Squared test

Statement	Chi-Square	p_value	Adjusted p_value	Significance
AI is essential in the medical field	38.72	0.00	0.00	TRUE
AI use in healthcare administrative work will have to comply with the data privacy laws in South Africa. There are serious privacy concerns with the use of AI	65.51	0.00	0.00	TRUE
AI has great potential for use in medical devices for diagnosis and prognosis and treatment.	95.79	0.00	0.00	TRUE
AI will replace physicians in the future	41.45	0.00	0.00	TRUE
The international harmonization of medical AI regulations is essential.	164.28	0.00	0.00	TRUE
AI in medical devices pose a higher risk of deviations from accuracy and safety and performance of medical devices	32.30	0.00	0.00	TRUE
A multi-stage regulatory review model by health authorities will be required to address safety & quality and efficacy concerns as AI systems are adaptive.	95.23	0.00	0.00	TRUE
AI will be essential in the fields of radiology and pathology	89.85	0.00	0.00	TRUE
The regulation of AI will be a burden to healthcare authorities	8.81	0.07	0.73	FALSE
The regulatory professional's role is important in the application and evaluation of medical AI.	127.96	0.00	0.00	TRUE
You have a keen interest to work on medical AI in the future	70.98	0.00	0.00	TRUE

Appendix G: Turnitin Digital Receipt and Originality Report



Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

Submission Author	Thirosha Chetty
Turnitin Paper ID (Ref. ID)	2623569430
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Assignment Title	Submission of final research report/dissertation/thesis to TurnitIn
Submission Date	24/03/25, 22:35

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