"Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor"

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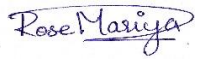
CANDIDATE DECLARATION

I hereby declare that this dissertation entitled "Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor," submitted in partial fulfilment of the requirements for the award of M.Sc. in Medical Device Technology and Business, is entirely my own work and is based on my independent study and research. I acknowledged all materials and sources used for the study. I certify that this work has not been copied, in whole or in part, from any other person's work, including that of other students, and has not been submitted previously for any academic qualification.

Student Signature: 

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Acknowledgements and Dedication

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
CGM	Continuous Glucose Monitor
FDA	Food and Drug Administration
MDR	Medical Device Regulation
EHR	Electronic Health Record
HIPAA	Health Insurance Portability and Accountability
EMA	European Medicines Agency
MARD	Mean Absolute Relative Difference
PMS	Post-Market Surveillance
SME	Small and Medium-sized Enterprises
PRO	Patient-Reported Outcome
RWE	Real World Evidence
MHRA	Medicines and Healthcare products Regulatory Agency
IoT	Internet of Things

ABSTRACT

Continuous Glucose Monitoring (CGM) systems have emerged as game-changing technologies in diabetes management, offering real-time glucose tracking, forecasting algorithms, and integrations with digital health platforms. Such technologies promise enhanced glycemic control, enhanced patient outcomes, and reduced dependency on traditional finger-prick glucose monitoring. However, introducing artificial intelligence (AI), cloud connectivity, and biosensor technology into CGM systems has ushered in complex regulatory problems, particularly within the European Union, based on the Medical Device Regulation (MDR 2017/745).

This study examines the nexus between CGM technology innovation and the changing European regulatory environment. It explores how technological innovations in AI, non-invasive biosensors, and telemonitoring are transforming diabetes care while also challenging the resilience and efficacy of existing regulatory structures. A qualitative approach was utilized, involving semi-structured interviews with influential stakeholders like healthcare practitioners, manufacturers, and regulatory professionals. Thematic analysis determined emerging challenges, opportunities, and stakeholder views.

Findings indicate an intense tension between accelerated innovation and regulatory adherence. Reclassification of CGMs as medical devices under the MDR has added documentation obligations, extended approval periods, and increased compliance costs, particularly onerous for SMEs. While stakeholders appreciate the value of safety and post-market surveillance, some are concerned that the MDR's stringency can hinder innovation, delay patient access to life-saving technology, and render the EU less competitive in the medtech sector. On top of that, AI validation protocol regulatory gaps, interoperable data standards, and cybersecurity framework weaknesses were repeatedly named as regulatory blind spots when it comes to CGM systems.

The study concludes by proposing adaptive regulatory strategies, such as low-risk CGM upgrade fast-track processes, more specific AI-specific validation guidelines, and greater cross-sectoral collaboration between developers and regulators. These measures could align innovation with regulation, rendering CGM technologies safe, accessible, and sensitive to patient needs.

This research contributes to the broader debate on digital health regulation. It provides practical recommendations to policymakers, regulators, and medtech innovators seeking to comply while promoting innovation in the CGM arena.

1 INTRODUCTION

Diabetes mellitus is a long-term metabolic disorder distinguished by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Globally, diabetes is a critical public health problem, with an estimated 537 million individuals having diabetes in 2021- a figure predicted to rise to 643 million by 2030 (International Diabetes Federation, 2024). This rise is attributed to physical inactivity, population ageing, and increasing obesity. Consequently, effective glucose monitoring has become central to modern diabetes management strategies.

Continuous Glucose Monitoring (CGM) systems are a key innovation, allowing real-time observation of interstitial glucose levels using minimally invasive sensors. They offer real-time reading and trend data and seamless integration with insulin pumps and digital health platforms for optimising glycemic control. As compared to the conventional finger-stick approach, CGMs offer dynamic glucose information and initial hypo- and hyperglycemia alerts and, therefore, meaningfully enhance patient outcomes(Jin *et al.*, 2023a; Klonoff *et al.*, 2024).

In Europe, CGM uptake is expanding, notably due to digital health and self-management policy stimuli. However, implementing the Medical Device Regulation (MDR 2017/745) has added complexity to the regulatory route. The MDR demands high levels of clinical evidence, extensive post-market surveillance, and software transparency, particularly daunting for AI-combined CGM technologies (Bretthauer *et al.*, 2023). AI algorithms' iterative updating and adaptive character clash with the inflexible regulatory structures, presenting obstacles to approval and market entry.

Furthermore, continuous glucose monitors (CGMs) provide constant health data streams, thereby requiring rigorous adherence to the General Data Protection Regulation (GDPR) and comprehensive cybersecurity protocols. As the healthcare model in Europe continues to adopt more interconnected health technologies, regulatory bodies have the arduous challenge of reconciling patient safety, technological advancement, and market access.

This thesis explores these converging fields- technological development of CGMs and the evolving European regulatory landscape. Through stakeholder analysis and qualitative data, the study discusses how AI-driven CGMs can be effectively and safely integrated into clinical

practice within the confines of current EU legislation. The general objective is to delineate balanced regulatory frameworks that foster innovation and safeguard public health.

1.1 BACKGROUND

Continuous Glucose Monitoring (CGM) technology has revolutionised the management of diabetes, offered comprehensive, real-time glucose data and reduced the necessity of conventional glucose testing to a bare minimum. The earliest CGM systems required frequent calibration and were beset by inaccurate results. However, with recent advances in sensor materials, wireless transmission, and predictive analytics- especially AI-driven- the performance and usability have significantly advanced(Jin *et al.*, 2023b; Yoo and Kim, 2023a).

Contemporary CGM systems are also compatible with mobile apps and wearable devices, facilitating patients' and clinicians' remote monitoring of continuous data. AI algorithms in CGMS have the potential to predict glycemic events, enabling timely intervention and preventing emergency hospitalisation. It has been shown that AI-powered CGMs can reduce hypoglycemic events and improve overall glycemic control by providing up to 30-minute pre-emptive alerts(Chan *et al.*, 2024). Despite these clinical benefits, the use of AI in medical devices has generated complex regulatory challenges within the European environment.

The Medical Device Regulation of the European Union (EU MDR 2017/745) has reclassified most CGMs into higher-risk classes, with rigorous requirements for clinical validation, cybersecurity, and post-market surveillance(Mathieu *et al.*, 2024) While intended to safeguard public health, these requirements disproportionately impact small and medium enterprises (SMEs), delaying innovation and market access.

Also, with CGMs increasingly relying on cloud connectivity and patient-generated data, they are under the scope of GDPR stipulations. These include ensuring patient consent, data portability, and protection from cyberattacks. Regulatory gaps in terms of AI validation, interoperability, and data security have caused stakeholders to question the EU's ability to keep pace with rapidly emerging digital health technologies (Espinoza *et al.*, 2023; Costa-Almeida and Almeida, 2024).

Thus, the intersection of AI, biosensor technology, and EU regulation creates a complex environment for CGM development. This study analyses how regulatory bodies can update frameworks to accommodate innovation without compromising patient safety or data integrity.

1.2 TITLE

Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor.

1.3 AIM

To investigate the regulatory challenges and technological advancements in Continuous Glucose Monitoring (CGM) systems, analyse their implications for market adoption, and propose solutions to balance innovation with regulatory compliance.

1.4 OBJECTIVES

1. To investigate recent technological advancements in CGMs, including sensors, AI, and connectivity.
2. To examine the EU's MDR controlling CGMs.
3. To identify challenges in balancing innovation with regulatory compliance.
4. To propose strategies to harmonize innovation with regulatory standards.

1.5 PURPOSE OF STUDY

This research explores the regulatory issues and technological innovation around Continuous Glucose Monitoring (CGM) systems within the European framework. As CGM technologies evolve at a fast pace, such as innovation in biosensors, artificial intelligence (AI), and wireless communication, there is an increasing demand to determine whether existing regulatory frameworks, especially the EU Medical Device Regulation (MDR), are adequate to foster innovation while ensuring device safety and effectiveness. This research examines regulatory compliance's influence on CGM development, approval timelines, and clinical adoption. It seeks to identify the significant challenges facing manufacturers and healthcare providers in balancing innovation and regulation. Through the integration of literature review, policy analysis, and stakeholder feedback, the research intends to propose solutions to harmonize technological development with regulatory expectations. The primary objective is to foster a regulatory climate that promotes innovation, expedites patient access to safe technologies, and improves the quality of diabetes care.

1.6 SIGNIFICANCE OF RESEARCH

This study highlights the critical intersection of regulation and innovation in diabetes technology. As CGM systems will only continue to grow more advanced, their regulation under the EU MDR brings significant concerns regarding flexibility and friendliness to

innovation. The study provides valuable insights to regulators, manufacturers, and clinicians by identifying current gaps in frameworks and proposing realistic avenues for bridging them. It informs academic and industry discourse around medical device regulation, with implications for policy reform and access to technology. Ultimately, the research supports making CGM innovation available to European patients safely, effectively, and equitably.

1.7 RESEARCH QUESTIONS

- What regulatory challenges affect the approval and integration of CGMs, especially AI-powered systems?
- How do these regulations influence technological innovation and market access?

1.8 RESEARCH OUTLINE

The dissertation is structured into the following chapters:

Chapter 2: Literature Review

This chapter reviews academic, regulatory, and industry literature on CGM devices through the themes of AI innovation, biosensor innovation, and the implications of EU Medical Device Regulation (MDR). It explores the regulatory landscape, areas of policy gaps, and innovations in CGM technologies. It offers a theoretical and empirical foundation by presenting the main challenges and opportunities in the CGM setting.

Chapter 3: Research Methodology

Describes the qualitative research method used in the research, taking an interpretivist stance. Explains why semi-structured interviews with the most significant stakeholders, like regulatory experts, manufacturers, and clinicians, are conducted. Describes the sampling approach, data gathering procedure, ethical considerations like GDPR compliance, and data analysis using thematic coding.

Chapter 4: Findings and Analysis

Report findings from qualitative interviews, structured around themes for key areas of regulatory compliance with MDR, AI integration in CGM systems, and market access challenges. Compares and critiques stakeholder perceptions with the literature, noting

points of concordance and tension, and outlines practical implications for regulation and innovation.

Chapter 5: Conclusions and Recommendations

The chapter summarises the main findings of the research and makes evidence-based recommendations to regulators, industry, and clinicians. It demands adaptive regulation, more open AI validation guidelines, and better stakeholder collaboration. The chapter also reflects on the research's contribution to the academic literature and suggests further research on digital health regulation.

2 LITERATURE REVIEW

2.1 INTRODUCTION

Research is the building block of scholarly research, presenting an orderly way to investigate multifaceted phenomena. For this dissertation, the literature review rigorously examines the key scholarly literature within the discipline, critiquing prevailing theories, methodologies, and research deficits. Through exploring earlier research, this section sets the academic background of the current study and supports its relevance.

Literature review is an essential research element that provides a complete integration of available and prior research. It determines trends, challenges, and debates characterising the scholarly literature. In evaluating various perspectives, this review bases the research on established knowledge and indicates areas needing further study.

Critical examination of existing literature enables researchers to locate their work in the broader academy. It discerns the positives and negatives of existing research, allowing scholars to build upon previous findings and respond to remaining challenges. Furthermore, it will enable researchers to narrow questions and build knowledge-based theories.

The literature review of this dissertation is thematic and addresses the most relevant studies and theories related to the research question. It criticises other methodological approaches, theoretical models, and empirical findings to provide a balanced analysis. In bringing together various opinions, this section shows the intricacy of the subject and emphasizes the need for further research.

Lastly, the literature review underpins the dissertation, guiding the research direction and ensuring the study is academically rigorous. It provides a framework for comprehending the

existing body of knowledge and establishing the importance of the research problem. By conducting a systematic literature review, this dissertation aims to fill gaps, test assumptions, and contribute to the academic discourse in the field.

KEYWORDS

Here are some key keywords commonly found in peer-reviewed articles related to my topic.

- Regulatory Challenges
- Medical Device Regulation (MDR)
- Continuous Glucose Monitoring (CGM)
- Artificial Intelligence
- Biosensors
- Non-Invasive Monitoring
- Cybersecurity
- Data Privacy
- Clinical Validation
- Safety Standards
- Market Access
- Reimbursement Policies
- Cost Issues
- Telemonitoring and Digital Health Integration
- Ethical and Legal Considerations
- AI Validation
- Healthcare Technology Regulations
- Diabetes Management
- Approval

2.2 TECHNOLOGICAL ADVANCEMENTS IN CONTINUOUS GLUCOSE MONITORING

Continuous Glucose Monitoring (CGM) has revolutionised diabetes management with real-time glucose tracking, artificial intelligence (AI) integration, and digital connectivity. The literature review addresses the newest technological developments in CGM, including biosensors, non-invasive monitoring, AI, telemonitoring, and cybersecurity. The abstracts of selected articles consolidate current knowledge, identify research gaps, and suggest enhancements to fortify CGM technology and regulatory compliance.

2.2.1 Biosensors and Non-Invasive Monitoring

(Yoo and Kim, 2023b) Discuss the application of CGMs in insulin-based diabetes treatment, focusing on advancements in glycaemic control. Sensor accuracy, patient compliance, and compatibility with insulin pumps are stressed in the study. Likewise, (Chan *et al.*, 2024) They

review optical, electrochemical, and transdermal sensors to discuss AI-based noninvasive blood glucose monitoring. They note AI's prospects for advancing non-invasive glucose sensing but recognise accuracy issues and regulatory challenges.

(Jin *et al.*, 2023a) Discuss biosensors utilised in CGMS, including enzymatic and non-enzymatic sensors. They address wearables and material science innovation, improving sensor biocompatibility and longevity (Huang *et al.*, 2024a) Discuss the technological advancement of wearable CGMs, emphasising microfluidic and nanotechnology-based sensors for high accuracy in non-invasive monitoring.

2.2.2 Artificial Intelligence (AI) and AI Validation

The use of AI in CGMs is exhaustively dealt with by (Chan *et al.*, 2024) and (Jin *et al.*, 2023a)including the utilisation of machine learning in glucose prediction and anomaly detection. Predictive analytics are enhanced with AI algorithms, yet validation remains challenging considering the varied patient responses. (Bergenstal, 2023) lays out a roadmap for CGM implementation, stressing the need for standard AI validation protocols to ensure clinical effectiveness.

(Espinoza *et al.*, 2023) argue for integrating CGM data into electronic health records, emphasizing the need for AI-driven data analysis. Their study identifies interoperability as a challenge and demands standardised data standards for enhancing AI-based decision-support systems in CGMs.

2.2.3 Telemonitoring and Digital Health Integration

(Jendle *et al.*, 2024) discuss interoperability challenges in CGM technology, appealing for greater digital health integration beyond regulatory lines. They highlight that CGM data must read and write seamlessly with insulin delivery devices and electronic medical records. Similarly,(Klonoff *et al.*, 2024) observe the demand for FDA-integrated CGMs to ensure accuracy, particularly in remote monitoring cases.

(Kompala *et al.*, 2023) discuss clinician attitudes to prescribing and interpreting CGM data. They show that while CGMs improve patient outcomes, limitations in data interpretation and data overload restrict adoption. Data visualization tools on digital health platforms must become more usable by clinicians and patients.

2.2.4 Cybersecurity and Data Privacy

Cybersecurity issues are addressed in several articles, such as (Meurant and Pleus, 2021) which sets out regulatory specifications for glucose self-monitoring devices. Data privacy is still a key area of concern, particularly with cloud-connected CGM devices. Emanuela (2024) points out new regulatory directions in data security, highlighting the need for cybersecurity guidelines reconcilable with healthcare regulation.

2.2.5 Gaps and Improvements

Category	Gaps Identified	Areas for Improvement
Biosensors and Non-Invasive Monitoring	• Accuracy challenges in optical and electrochemical sensors. • Variability in patient physiology affects sensor performance. • Limited biocompatibility and sensor longevity • Lack of standardized clinical validation protocols	• Develop improved calibration techniques to enhance accuracy. • Research into more stable biomaterials and self-calibrating sensors. • Establish standardized regulatory guidelines for non-invasive CGMs.
Artificial Intelligence (AI) and AI Validation	• Lack of standardized AI validation protocols • AI models struggle with physiological variability across populations • Poor interoperability with health systems due to non-standardized data formats (Espinoza et al., 2023).	• Develop universal AI performance assessment frameworks. • Enhance AI adaptability to individual patient profiles. • Create standardized APIs for seamless AI integration with EHRs.
Telemonitoring and Digital Health Integration	• Interoperability challenges between CGMs, insulin delivery devices, and EHRs • Clinician's difficulty in interpreting large amounts of CGM data	• Standardize data-sharing protocols for better integration. • Improve data visualization tools and AI-

	• Accuracy concerns in remote monitoring environments	assisted alerts for easier interpretation. • Enhance sensor accuracy and stability under different environmental conditions.
Cybersecurity and Data Privacy	• Lack of robust cybersecurity frameworks, making CGMs vulnerable to hacking • Regulatory gaps in CGM data protection across regions • Unclear patient consent and data ownership regulations	• Implement AI-driven anomaly detection for cybersecurity. • Develop global harmonised standards for CGM data security. • Establish clearer patient-centred data governance policies.

Table 2-1 Gaps and Improvements in Technological Advancements in CGM by the author

2.2.6 Key Insights

Technology in Continuous Glucose Monitoring (CGM) has transformed diabetes management with real-time monitoring of glucose, integration with AI, and digital connectivity for health. Advances in biosensors and non-invasive sensing(Yoo and Kim, 2023b; Chan *et al.*, 2024)reflect increased sensor accuracy, biocompatibility, and solutions based on nanotechnology, although accuracy and regulatory issues still prevail.

The application of AI in CGMs (Jin *et al.*, 2023a; Chan *et al.*, 2024) is explored in glucose forecasting with machine learning, but problems continue for AI validation and interoperability with electronic health records (Espinoza *et al.*, 2023). Integration with digital health and telemonitoring (Jendle *et al.*, 2024) require more interoperability between insulin pumps, CGMs, and clinical systems, while the burden of data prevents uptake (Kompala *et al.*, 2023).

Cybersecurity and data privacy concerns (Meurant and Pleus, 2021; Emanuela, 2024)direct towards robust security systems. Homogeneous cybersecurity policies and AI-based defenses are essential to upholding data integrity in cloud-connected CGMs.

2.2.7 Summary

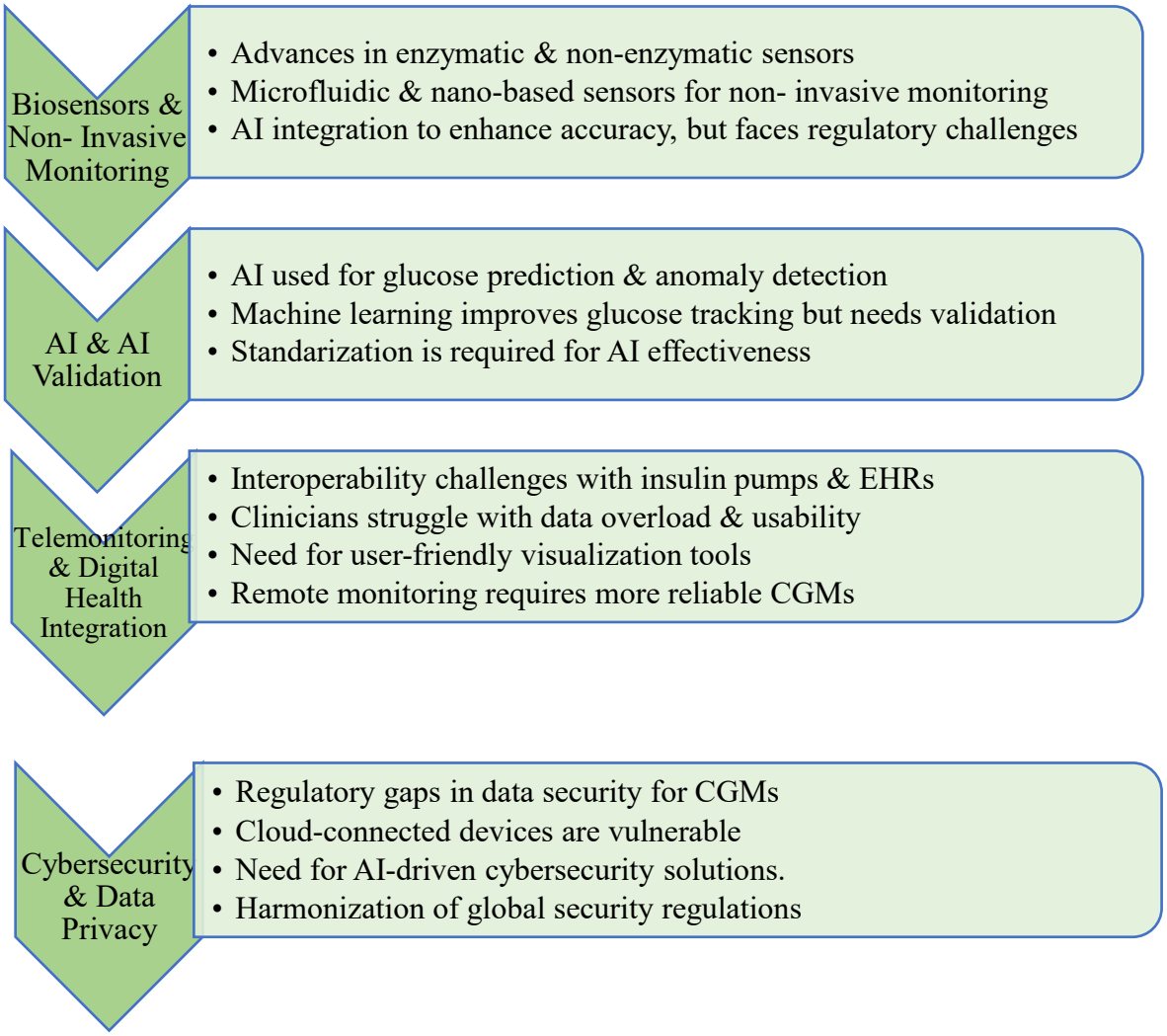


Figure 2-1 Summary of Technological Advancements in CGM by the author

2.3 REGULATORY FRAMEWORK FOR CGMS UNDER THE EU MEDICAL DEVICE REGULATION (MDR)

Continuous Glucose Monitoring (CGM) has also seen considerable evolution in diabetes care, with advancing technologies that have the potential to deliver better glycemic control for patients on insulin therapy. The above articles clearly show where CGM is now, from its integration with Artificial Intelligence (AI) to regulatory routes and marketplace entry. This research can be critically examined across such critical topics as regulation of healthcare technology, clinical validation and safety needs, procedures for approval, access to marketing, and ethical/legal concerns.

2.3.1 Healthcare Technology Regulations

Health regulations for medical technology are significant to guarantee that the safety and efficiency of CGMs are maximised in the marketplace. For the EU Medical Device Regulation (MDR), CGMs must undergo strict qualifications before they become eligible for market availability. For instance, the "Minimum expectations for market authorisation of continuous glucose monitoring devices in Europe" article depicts the compliance status of eCGM devices based on the conditions that devices ought to meet a set of requirements of accuracy, durability, and usability(Mathieu *et al.*, 2024a) All these requirements match the European Union's MDR, which calls for clinical trials and rigorous tests of devices before they can be approved for use by the general public.

AI-based innovations in CGMs, as outlined in "AI-Based Non-invasive Blood Glucose Monitoring: Scoping Review" (Chan *et al.*, 2024) Indicate directions for future trends in non-invasive glucose monitoring that could disrupt traditional CGM systems. However, the regulatory structures for such new devices are less advanced, requiring an update of current healthcare regulations to accommodate AI-based technologies.

2.3.2 Clinical Validation and Safety Standards

Clinical validation and safety standards are the most imperative aspects of the medical device regulation, and most crucially, CGMs. Continuous glucose monitoring systems must demonstrate accuracy and reliability to ensure that information provided to users is credible. Clinical validation of CGM devices is discussed in the article "Advances in Continuous Glucose Monitoring and Integrated Devices for Management of Diabetes with Insulin-Based Therapy"(Yoo and Kim, 2023a) where the improvement of glycemic control is discussed, i.e., reduction in A1C level and reduction in hypoglycemia events. Clinical validation ensures devices provide correct glucose measurements and operate safely under various conditions.

The research paper "Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy of Continuous Glucose Monitoring" (Klonoff *et al.*, 2024) discusses how regulatory bodies like the FDA guarantee the accuracy of CGM sensors. Incorporating CGMs into other healthcare information systems, including electronic health records (EHRs), is crucial to improving patient outcomes. Such systems are subjected to stringent safety requirements to be utilized within agreed-upon parameters.

2.3.3 Approval Processes and Market Access

The regulatory process to gain EU MDR approval for CGMs is described in "Minimum expectations for market authorisation of continuous glucose monitoring devices in Europe." Several steps in the regulatory process involve pre-market evaluation, clinical trials, and post-market surveillance. The approval process is stringent since there is potential danger from inaccurate readings of glucose, which can lead to severe health consequences like diabetic ketoacidosis or hypoglycemia.

The article "Diabetes Specialists Value Continuous Glucose Monitoring Despite Challenges in Prescribing and Data Review Process"(Kompala *et al.*, 2023) refers to the challenge that healthcare providers face in interpreting the data from the CGM and the barrier in prescribing devices. Healthcare policy, insurance coverage by companies, and patients' access to the latest technologies also limit access to the market for CGMs. These problems underline the need for an improved regulatory system that strikes a better balance between the convenience of access and safety to CGM technology.

2.3.4 Ethical and Legal Considerations

Ethical and legal considerations of CGMs are essential, particularly patient confidentiality, data protection, and informed consent. Since CGMs provide real-time data streams, data storage and sharing must adhere to strict data protection legislation, such as the EU's General Data Protection Regulation (GDPR). The "A Narrative Commentary About Interoperability in Medical Devices and Data Used in Diabetes Therapy" article (Jendle *et al.*, 2024) encapsulates the interoperability challenges, ensuring CGM data is securely shareable on different platforms without compromising patient privacy.

Besides, the ethical implications of AI-based CGMs, as mentioned in the article "Artificial Intelligence Biosensors for Continuous Glucose Monitoring" (Jin *et al.*, 2023a)are problematic in terms of algorithmic bias and data misuse. These aspects must be regulated cautiously to use the technology ethically and safeguard the patient's rights.

2.3.5 Gaps and Improvements

Gaps	Improvements
Lack of Clear Guidelines for AI and Non-invasive Devices	**Develop Specific Guidelines for AI-Based and Non-invasive CGMs**: Regulatory bodies like the EMA should create specific regulations to ensure AI-based and non-

	invasive CGMs undergo appropriate clinical validation and safety testing.
Lengthy and Resource-Intensive Approval Process	**Streamline the Approval Process for Low-Risk Devices**: Introduce accelerated approval pathways for incremental innovations, making the approval process faster and more efficient for low-risk devices.
Insufficient Interoperability Standards	**Enhance Interoperability Standards**: Standardize the interoperability of CGM systems with other medical devices and EHRs to ensure seamless data exchange and improve patient outcomes.
Limited Data Protection and Privacy Regulations for CGM Data	**Strengthen Data Privacy Regulations**: Introduce stricter data protection protocols to safeguard patient privacy, especially in the context of AI-based CGMs and the continuous flow of health data.
Inconsistent Ethical Guidelines for AI in CGM Devices	**Address Ethical Concerns**: Establish standardized ethical guidelines to ensure transparency in AI algorithms, informed consent, and data usage for CGMs, minimizing risks of algorithmic biases and data misuse.
Unclear Regulatory Pathways for Emerging Technologies	**Create Clear Pathways for Emerging Technologies**: Adapt the regulatory framework to address the unique challenges posed by AI, non-invasive technologies, and wearables in the CGM market.
Limited Consideration for Real-World Effectiveness and Patient Experience in Regulatory Reviews	**Incorporate Real-World Effectiveness and Patient Feedback**: Use real-world data and patient experience surveys to validate the effectiveness of CGM devices, ensuring that regulatory reviews reflect actual patient outcomes.

Table 2-2Gaps & Improvements of Regulatory Framework for CGMs under EU (MDR)

2.3.6 Key Insights

CGM technology is improving, yet regulatory systems must keep up with enhancing safety, effectiveness, and availability. EU MDR necessitates strict adherence, but AI-powered, non-invasive CGMs face regulatory deficits in conforming (Mathieu *et al.*, 2024a; Chan *et al.*, 2024). Clinical verification matters, with accuracy in glycemic management (Yoo and Kim, 2023a). However, EHR integration and security problems remain (Klonoff *et al.*, 2024). The regulatory approval is stringent, yet market entry is constrained by insurance and reimbursement barriers (Kompala *et al.*, 2023). Additionally, GDPR and AI ethics issues relate to algorithmic bias and data privacy (Jin *et al.*, 2023a; Jendle *et al.*, 2024) sealing these gaps

with updated rules, improved reimbursement practices, and improved data security will lead to safer and more available CGMs, which will benefit diabetes care and patient well-being.

2.3.7 Summary

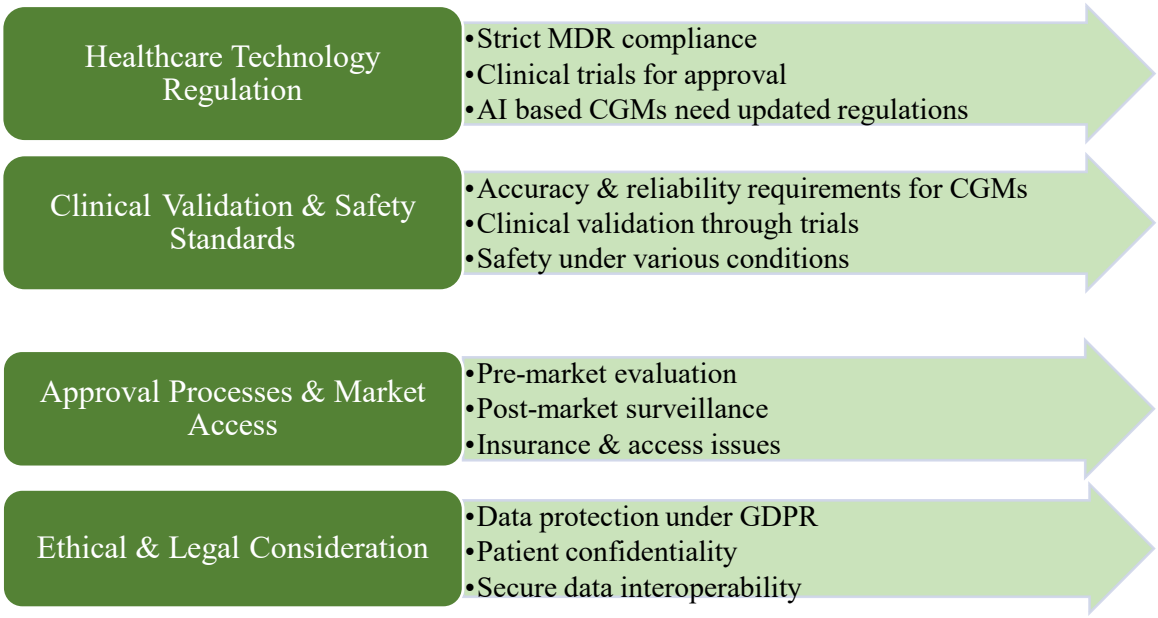


Figure 2-2 Summary of Regulatory Framework for CGMs under EU (MDR) by author

2.4 CHALLENGES IN BALANCING INNOVATION AND REGULATORY COMPLIANCE

Continuous Glucose Monitoring (CGM) has revolutionized diabetes management, particularly for insulin-treated patients. As CGM technologies continue to improve alongside their integration with Artificial Intelligence (AI), wearables, and noninvasive devices, balancing innovation and adherence remains an ongoing challenge. The following articles highlight some of these challenges and opportunities, with a central theme revolving around cost considerations, reimbursement policy, AI validation and regulatory approval, cybersecurity and data privacy, and patient safety.

2.4.1 Cost Issues and Reimbursement Policies

Cost concerns and reimbursement policies are significant barriers to widely adopting CGM systems. In the paper "Diabetes Specialists Value Continuous Glucose Monitoring Despite Challenges in Prescribing and Data Review Process," (Kompala *et al.*, 2023) describe how the cost of CGM devices can discourage healthcare providers from prescribing them, particularly for lower-income or underinsured patients. Reimbursement policies often do not cover the entire cost of these newer technologies, limiting patient access to life-saving devices.

The article "Minimum expectations for market authorization of continuous glucose monitoring devices in Europe" (Mathieu *et al.*, 2024a) points to the necessity for regulatory frameworks to consider the cost-effectiveness of CGMs and integrate these systems into healthcare on the basis of reimbursement schemes. These frameworks are required to ensure that reimbursement guidelines can keep up with the pace of technology development, enabling patients to access innovative devices without placing a financial burden.

2.4.2 AI Validation and Regulatory Approval

AI-powered CGM devices hold the potential of more accurate and predictive blood glucose monitoring, but regulatory approval of AI devices is a significant stumbling block. The article "AI-Based Noninvasive Blood Glucose Monitoring: Scoping Review" (Chan *et al.*, 2024) summarizes the challenge of validating artificial intelligence algorithms employed in noninvasive CGM devices. Unlike traditional devices, AI devices require strict validation that their predictions are stable and correlate with clinical outcomes.

"Artificial intelligence biosensors for continuous glucose monitoring" (Jin *et al.*, 2023a) gives a detailed overview of AI's potential in CGM but emphasises the absence of well-established regulatory routes for AI-driven devices. Regulatory bodies like the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have not yet created overarching guidelines dealing with AI system validation in medical devices. Lack of certainty in clear guidelines can delay the introduction of AI-based CGMs, thus hindering innovation.

2.4.3 Cybersecurity and Data Protection Compliance

As CGMs become integral to digital health ecosystems, patient data security is a top priority. Paper "A Narrative Commentary About Interoperability in Medical Devices and Data Used in Diabetes Therapy" (Jendle *et al.*, 2024) discusses the challenge of keeping CGM systems in line with regulatory standards for cybersecurity and data protection regulations. Because these devices collect and transmit confidential patient data, they must comply with privacy statutes such as the EU's General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA) in the United States.

The article "The Need for Data Standards and Implementation Policies to Integrate CGM Data into the Electronic Health Record"(Espinoza *et al.*, 2023) emphasizes the need to formulate strict standards regarding privacy and data security. Because CGM data is transferred from device to device and platforms, it is essential to confirm that patient details are kept encrypted, protected against breaches, and accessed only for the intended use.

2.4.4 Diabetes Management and Patient Safety

Safety is of major importance for patients during the design of CGM. The article "Advances in Continuous Glucose Monitoring and Integrated Devices for Management of Diabetes with Insulin-Based Therapy" by (Yoo and Kim, 2023b) illustrates how using CGMs and insulin therapy combined might improve glycemic control. Their safety and accuracy, however, are key to this, as misreading glucose concentration might have disastrous medical implications, including causing hypoglycemia or diabetic ketoacidosis.

The challenge from a regulatory perspective is ensuring that CGM systems are sufficiently stringent from a safety standpoint while still permitting innovation. As the article "Roadmap to the Effective Use of Continuous Glucose Monitoring" (Bergenstal, 2023) Points out, regulatory frameworks have to balance innovation with protecting patient safety through strong clinical validation and post-market surveillance.

2.4.5 Gaps and Recommendations

Challenges	Gaps	Recommendations
Cost Issues and Reimbursement Policies	Lack of reimbursement policies for emerging CGM technologies is limiting patient access to advanced devices.	**Update Reimbursement Policies**: Adapt reimbursement structures to cover new CGM devices, ensuring accessibility for all patients.
AI Validation and Regulatory Approval	Insufficient and unclear guidelines for validating AI-based CGMs are delaying market access for AI-driven innovations.	**Develop Clear Guidelines for AI-Based CGMs**: Establish standardized regulatory frameworks for AI CGM validation to accelerate approval processes.
Cybersecurity and Data Protection Compliance	Inconsistent or inadequate data protection and cybersecurity regulations for CGM systems and integrated devices.	**Implement Standardized Data Protection Guidelines**: Develop robust cybersecurity protocols and data protection laws to ensure patient privacy across all platforms.
Diabetes Management and Patient Safety	Incomplete safety standards for integrated CGM systems, potentially jeopardizing patient safety and treatment outcomes.	**Strengthen Safety Standards and Post-Market Surveillance**: Enforce rigorous safety standards for CGM devices and ensure continuous post-market monitoring.

Table 2-3 Gaps & Recommendations in Challenges in Balancing Innovation and Regulatory Compliance by the author

2.4.6 Key Insights

Finding a balance between innovation and regulatory compliance for Continuous Glucose Monitoring (CGM) remains challenging, especially with the inclusion of AI. Cost barriers restrict accessibility, as (Kompala *et al.*, 2023) highlight, with reimbursement policies not accounting for costs. (Mathieu *et al.*, 2024a) highlight the need for cost-reducing regulatory strategies to expand accessibility. AI verification also poses a challenge, with (Chan *et al.*, 2024) detailing issues about assurances of predictive accuracy and (Jin *et al.*, 2023a) mentioning a lack of transparency from the FDA and EMA guidelines, bringing AI-enabled CGMs to a halt. Cybersecurity is also an issue, with demands for more security of data by (Espinoza *et al.*, 2023; Jendle *et al.*, 2024) via GDPR and HIPAA, respectively. Lastly, patient safety remains a priority, as (Yoo and Kim, 2023b) emphasize CGMs' role in glycemic control, while (Bergenstal, 2023) demands stringent clinical validation and post-market surveillance for safe yet innovative CGM development.

2.4.7 Summary

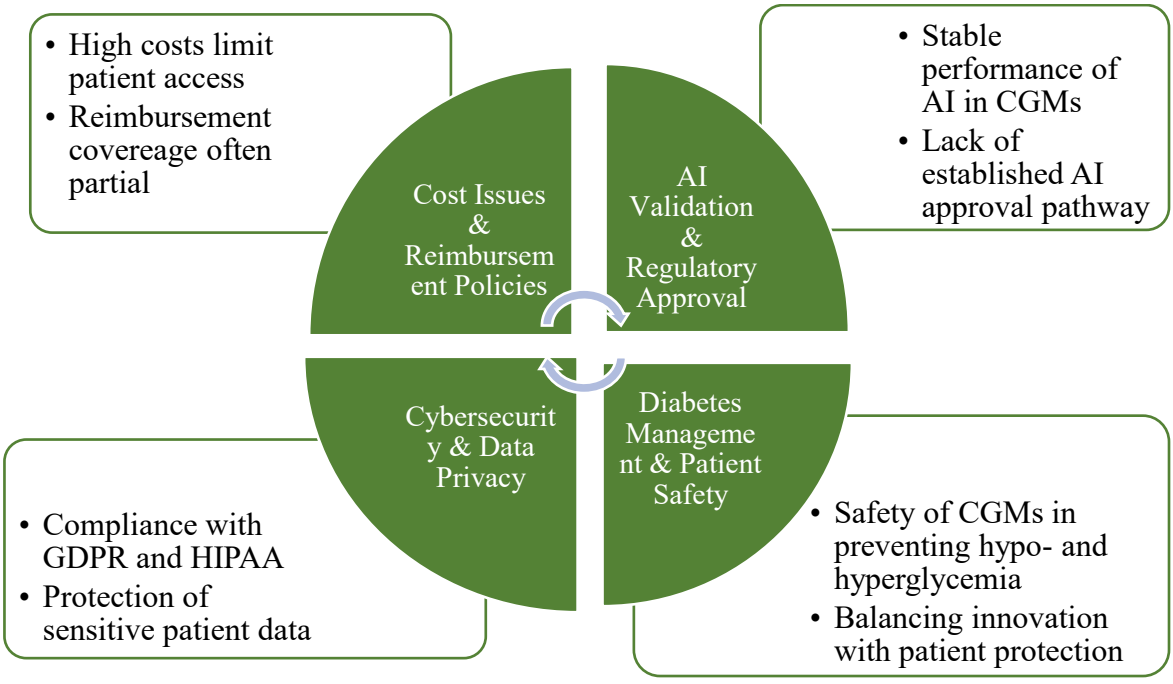


Figure 2-3 Summary of Challenges in Balancing Innovation and Regulatory Compliance by the author

2.5 STRATEGIES TO HARMONIZE INNOVATION WITH REGULATORY STANDARDS

The development of Continuous Glucose Monitors (CGMs), especially those with Artificial Intelligence (AI) technologies, promises tremendous improvements in diabetes care. However, as innovation in this technology advances, regulatory processes must catch up without undermining product performance and patient safety. The following articles cover the critical

challenges of balancing innovation and regulatory considerations in CGMs, such as AI technologies, clinical validation, data security, and market access.

2.5.1 Regulatory Pathways for AI-driven CGMs

AI-based CGMs provide more predictive and accurate glucose monitoring, but regulatory progress for such technologies is uncertain. In "AI-Based Noninvasive Blood Glucose Monitoring: Scoping Review"(Chan *et al.*, 2024) the challenge of AI technology regulatory approval, particularly the nonavailability of established pathways for medical devices reliant on AI, is discussed. AI algorithms must be tested for accuracy and consistency, but current regulatory procedures are not sufficient to handle the subtleties of AI-driven healthcare products. In addition, the article "Artificial Intelligence Biosensors for Continuous Glucose Monitoring" (Jin *et al.*, 2023a) identifies the need for regulatory bodies to review their frameworks to accommodate the unique challenges posed by AI and biosensors in CGM.

2.5.2 Optimizing Clinical Validation for Faster Approval

Clinical validation is essential for ensuring the safety and efficacy of CGM devices, particularly for new technologies like AI-driven systems. The article "Advances in Continuous Glucose Monitoring and Integrated Devices for Management of Diabetes with Insulin-Based Therapy" (Yoo and Kim, 2023b) emphasises the importance of rigorous clinical trials to validate the effectiveness of new CGMs in improving glycemic control. However, the clinical trial process for new technologies is often slow and costly, delaying the market introduction of potentially life-saving devices. The article "Minimum Expectations for Market Authorisation of Continuous Glucose Monitoring Devices in Europe- ‘eCGM’ Compliance Status"(Mathieu *et al.*, 2024a) discusses how regulatory authorities need to streamline the clinical validation process, especially for devices used alongside insulin therapy.

2.5.3 Enhancing Data Privacy While Enabling Connectivity

CGMs gather and share enormous amounts of sensitive healthcare data. With increasingly interconnected CGMs through apps, cloud-based computing services, and other web-based platforms, data privacy is a critical concern. The article "A Narrative Commentary About Interoperability in Medical Devices and Data Used in Diabetes Therapy"(Jendle *et al.*, 2024) outlines conflicts between data security preservation and enabling device-to-device and device-to-system communication. Regulatory bodies must implement strong data protection protocols, especially in the context of GDPR in the EU and HIPAA in the U.S., to maintain patient protection while enabling the connectivity required in newer CGM technologies.

2.5.4 Facilitating Market Access Through Standardized Compliance Approaches

Different regulatory requirements must be met for CGMs to be able to reach markets in various geographical areas. The necessity for standardized standards to make it easier for CGM devices to enter the worldwide market is highlighted in the paper "Regulatory Profile for Glucose Self-Monitoring Tools"(Meurant and Pleus, 2021). Diverse regulatory frameworks in the US, EU, and other international markets might make it difficult to obtain and postpone the release of cutting-edge CGM technology. By facilitating quicker and easier market access, standardized compliance strategies may guarantee that patients everywhere can take advantage of the most recent developments.

2.5.5 Gaps and Recommendations

Challenges	Gaps Identified	Recommendations for Improvement
Regulatory Pathways for AI-driven CGMs	- Lack of clear regulatory pathways for AI-based CGMs. - No standardized validation criteria for AI-driven glucose monitoring.	- Develop AI-specific regulatory frameworks for CGMs (e.g., EU MDR, FDA). - Define risk-based validation requirements for AI models.
Optimizing Clinical Validation for Faster Approval	- Lengthy and costly approval processes. - No fast-track pathways for CGMs with incremental innovations.	- Introduce expedited approval pathways for low-risk modifications of existing CGMs. - Use real-world data for post-market validation.
Enhancing Data Privacy While Enabling Connectivity	- Inconsistent global data privacy regulations (e.g., GDPR vs HIPAA). - Cybersecurity risks due to increased connectivity of CGMs.	- Develop unified global data protection standards. - Mandate end-to-end encryption and secure cloud storage for CGM data.
Facilitating Market Access Through Standardized Compliance Approaches	- Varying regulations across regions slow down CGM market entry. - Lack of harmonized compliance frameworks for CGMs.	- Establish international regulatory alignment through IMDRF. - Encourage mutual recognition of CGM certifications across major markets.
Cybersecurity and Data Protection Compliance	- AI-powered CGMs are vulnerable to hacking and unauthorised data access. - Lack of clear cybersecurity	- Implement mandatory cybersecurity risk assessments for CGMs. - Software updates and AI model

	guidelines for wearable medical devices.	audits are required as part of regulatory compliance.
Cost Issues and Reimbursement Policies	- The high cost of CGMS limits access for patients. - Lack of insurance coverage or inconsistent reimbursement policies across different regions.	- Advocate for broader insurance coverage of CGMs. - Develop cost-effective CGM models with accessible pricing for broader adoption.
Diabetes Management and Patient Safety	- Limited real-world studies on the long-term safety of AI-driven CGMs. - Potential over-reliance on AI-generated glucose predictions.	- Conduct longitudinal studies on AI-integrated CGMs. - Establish user guidelines to prevent excessive dependence on AI-generated predictions.

Table 2-4 Gaps & Recommendations in Strategies to Harmonize Innovation with Regulatory Standards by author

2.5.6 Key Insights

The development of AI-based Continuous Glucose Monitors (CGMs) brings notable advances in diabetes management. Still, regulatory systems need to be adapted to balance patient protection with the prevention of innovation blockage. Regulatory approval for AI-based CGMs is challenging due to the lack of standard frameworks, as pointed out by (Chan *et al.*, 2024), who advocate for new frameworks to evaluate the reliability and responsiveness of AI in healthcare. Also, clinical verification continues to be a cumbersome yet necessary procedure, slowing the introduction into the market for possibly lifesaving CGMs. (Yoo and Kim, 2023a) Place the weight of focus on scrupulous trials, while (Mathieu *et al.*, 2024a) Discuss the trade-offs surrounding condensed verification methods with a view toward accelerated approval. Data privacy is still an overwhelming priority since CGMs are becoming increasingly app- and cloud-supported. (Jendle *et al.*, 2024) Argued that regulations like GDPR and HIPAA need to be reinforced to safeguard patient data while ensuring smooth interoperability. Lastly, various degrees of global regulation create market-access obstacles.(Meurant and Pleus, 2021) favour imposing standardised methods of compliance to make AI-based CGMS more widely used.

2.5.7 Summary

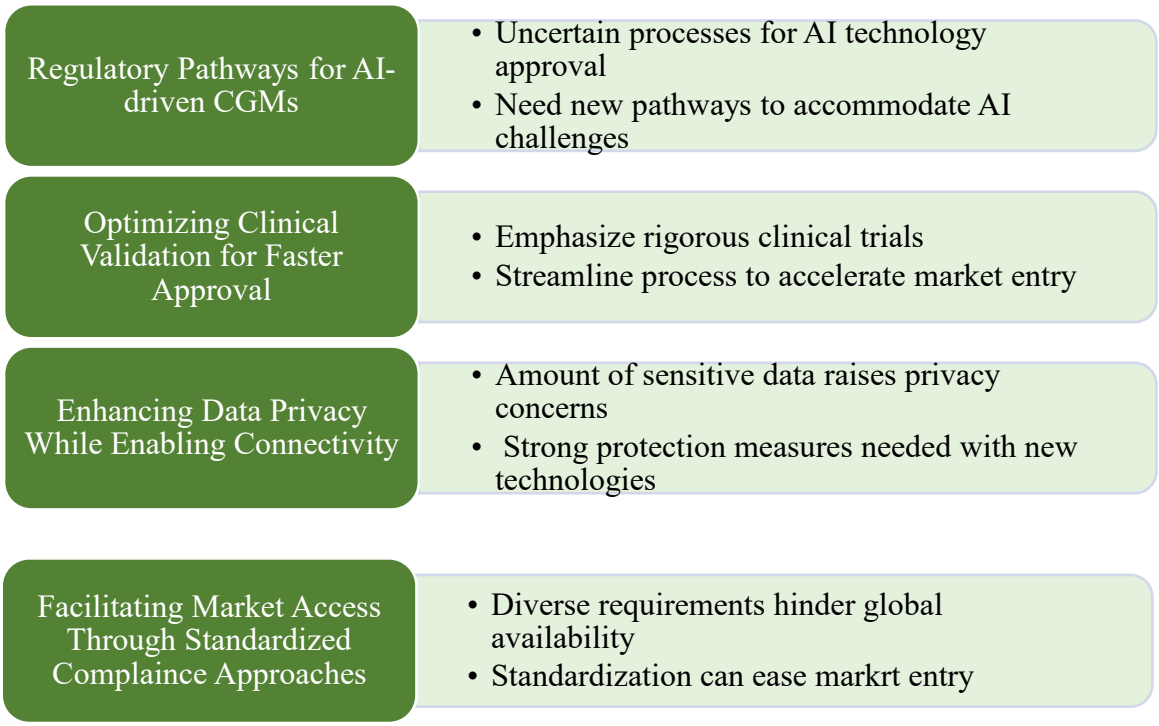


Figure 2-4 Summary of Strategies to Harmonize Innovation with Regulatory Standards by author

2.6 CONCEPTUAL FRAMEWORK

This diagram outlines key considerations in the evolving environment of Continuous Glucose Monitoring (CGM) systems. It highlights the intersection between regulatory frameworks, technological innovation, market access challenges, and the need to balance innovation against regulatory scrutiny for efficient and equitable adoption.

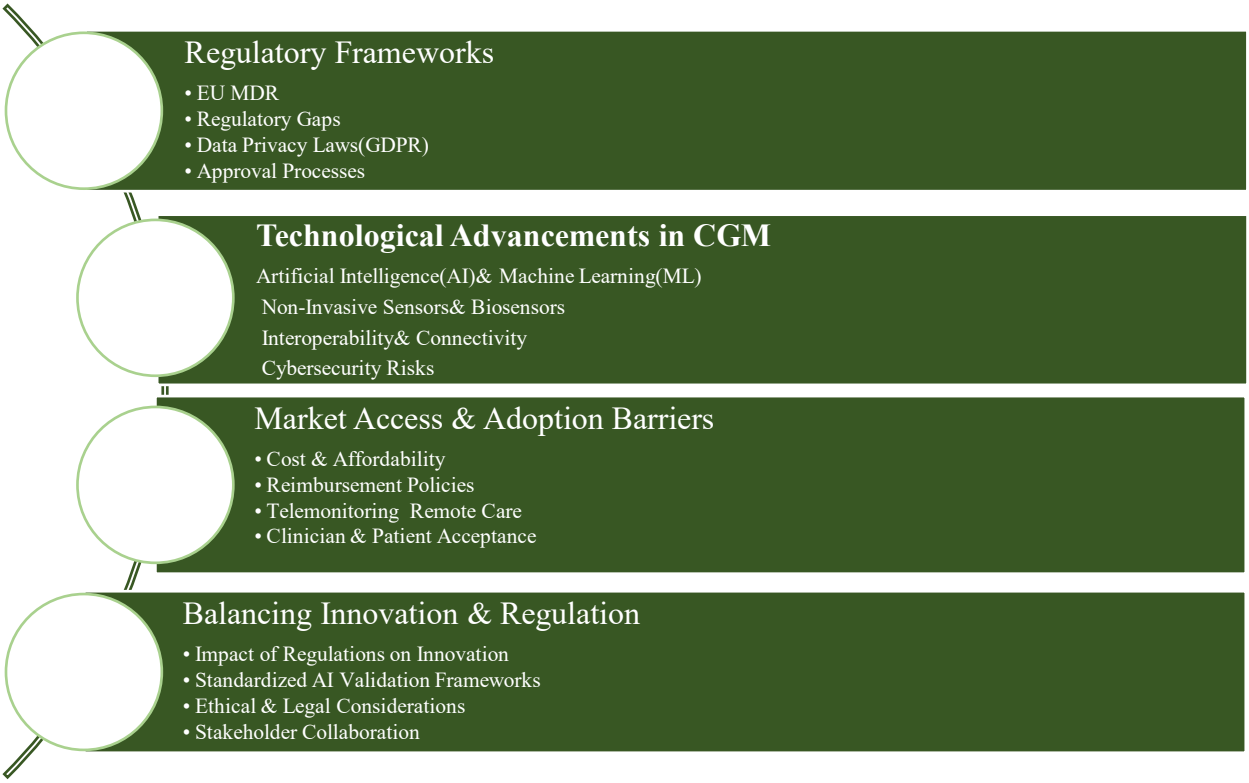


Figure 2-5 Conceptual Framework by the author

2.7 CONCLUSION

This literature review has covered key developments, challenges, and opportunities in the sector, offering a detailed examination of current research. The findings indicate that while there has been significant progress, there remain considerable gaps that need to be addressed. These include inconsistencies in regulatory frameworks, limitations in market access, and challenges in integrating emerging technologies with legacy systems. Despite these difficulties, the literature reports a heightened emphasis on innovation, particularly in artificial intelligence, data security, and clinical validation. One of the primary conclusions from this review is the need for a more structured process of harmonizing regulatory compliance with technological innovation. The rapid rate at which technologies are being developed always seems to be ahead of policy and regulation development, thus creating a gap that can encroach on the effective deployment of new solutions. Ensuring that regulatory bodies can keep pace with the rate of change without stifling innovation is necessary to make progress in this space.

Additionally, the review highlights the necessity for collaboration between stakeholders, including researchers, policymakers, and industry players. Through collaboration, stakeholders can develop harmonized protocols that facilitate market entry while ensuring safety and

efficacy requirements are maintained. Future research should be directed towards simplifying such processes to allow seamless integration of new technologies.

In conclusion, although considerable advancements have been achieved, ongoing efforts are needed to surmount current challenges. These challenges need to be addressed through systematic regulatory reforms, enhanced industry cooperation, and responsive policies that will be crucial in ensuring continued progress. This review establishes a solid base for subsequent discussions and research toward promoting innovation without compromising on necessary regulatory requirements.

3 RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter presents the methodological foundation underpinning the research investigating regulatory challenges and technological innovation in Continuous Glucose Monitoring (CGM) systems. Adopting the Saunders' Research Onion model, the research theoretically demarcates its philosophy, approach, strategy, and data collection instruments to ensure methodological coherence. The research adopted an interpretivist philosophy, recognising the regulatory environment and technology adoption as socially constructed phenomena best understood through stakeholders' experiences. The study followed an inductive route, with findings and conclusions generated from the data instead of testing pre-existing hypotheses. A qualitative approach comprising semi-structured interviews was used to obtain in-depth accounts from healthcare professionals, manufacturers, and regulators. The cross-sectional timescale enabled a snapshot of stakeholder experiences in the rapidly evolving environment of CGM regulation. Ethical approval, informed consent, anonymisation, and adherence to GDPR guidelines were rigorously followed. This strategy ensures the study's reliability, validity, and ethical integrity, providing rich information that comprehensively addresses the research objectives.

3.2 RESEARCH METHODOLOGY

3.2.1 Research Process

The research method of this study is qualitative and exploratory to understand the regulatory problems and technological innovation of Continuous Glucose Monitoring (CGM) systems. The study begins with a thorough literature review to analyse the existing studies' gaps and form a conceptual backdrop. This is followed by primary research to get firsthand information

straight from the stakeholders directly involved in the development, regulation, and utilization of CGM.

The primary research includes semi-structured interviews, which provide a detailed but flexible data collection method. This format enables the researcher to guide the conversation with pre-set questions but allows respondents' autonomy to elaborate on concerns that they consider significant. Interviewees can be regulatory specialists, producers of CGM, or medical practitioners, so that opinions from diverse categories are included. This method is beneficial in exploring such intricate issues as compliance, innovation, and policy interpretation in an ever-changing technological and regulatory environment.(Mathieu *et al.*, 2025).

Data collected from these interviews is later transcribed and analyzed using thematic analysis to identify recurring themes and patterns. This research ensures findings are based on existing practice and contribute substantially to the discourse of regulatory innovation in medical technology.(Omeihe and Harrison, 2024).

3.2.2 Research Design

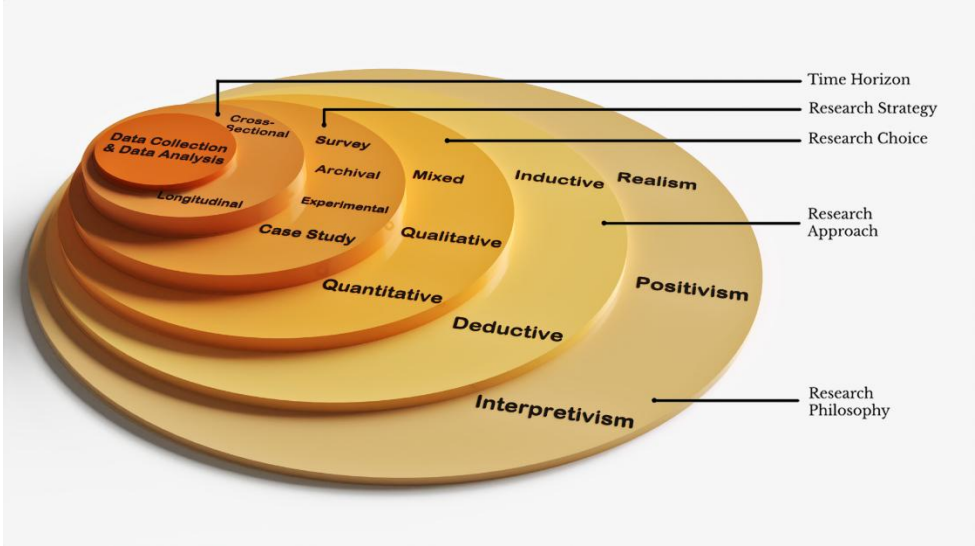
Research design is the strategy of how the research was conducted, to ensure consistency between the research philosophy, approach, and methodology (Bell *et al.*, 2022). This study's qualitative research design follows an interpretivist philosophy and applies an inductive research approach. Research design will likely fall under qualitative, quantitative, or mixed-methods paradigms. Due to the exploratory nature of this study, examining the regulatory challenges and technological enhancements of Continuous Glucose Monitoring (CGM) systems, a qualitative design was taken to gain insight into subjective experiences and stakeholders' complicated, context-dependent views.

Based on Saunders' research onion (Fig. 3-1), research methods are categorised under positivism, post-positivism, critical realism, and interpretivism. Conversely, Interpretivism accepts that reality is socially constructed and is concerned with understanding meaning and experience. This study is geared to interpretivism since it seeks to uncover how different actors, manufacturers, healthcare providers, and regulators interpret and negotiate regulatory frameworks amid evolving CGM technology (Junjie and Yingxin, 2022a).

An inductive methodology was followed, in which conclusions and theoretical insights were formulated from the data collected instead of being tested with pre-established hypotheses.

Inductive reasoning is particularly apt, given the scarce theoretical frameworks covering AI-driven CGMs in the context of present EU MDR requirements.

A qualitative research design aligns with the interpretivist stance, delivering depth instead of breadth. Semi-structured interviews were selected as the primary data collection method, allowing participants the latitude to elaborate on and explore their experiences, and maintaining consistency with dominant research themes. (Jin *et al.*, 2023a). The method facilitates an in-depth exploration of the intersection of technology, regulation, and real-world application.



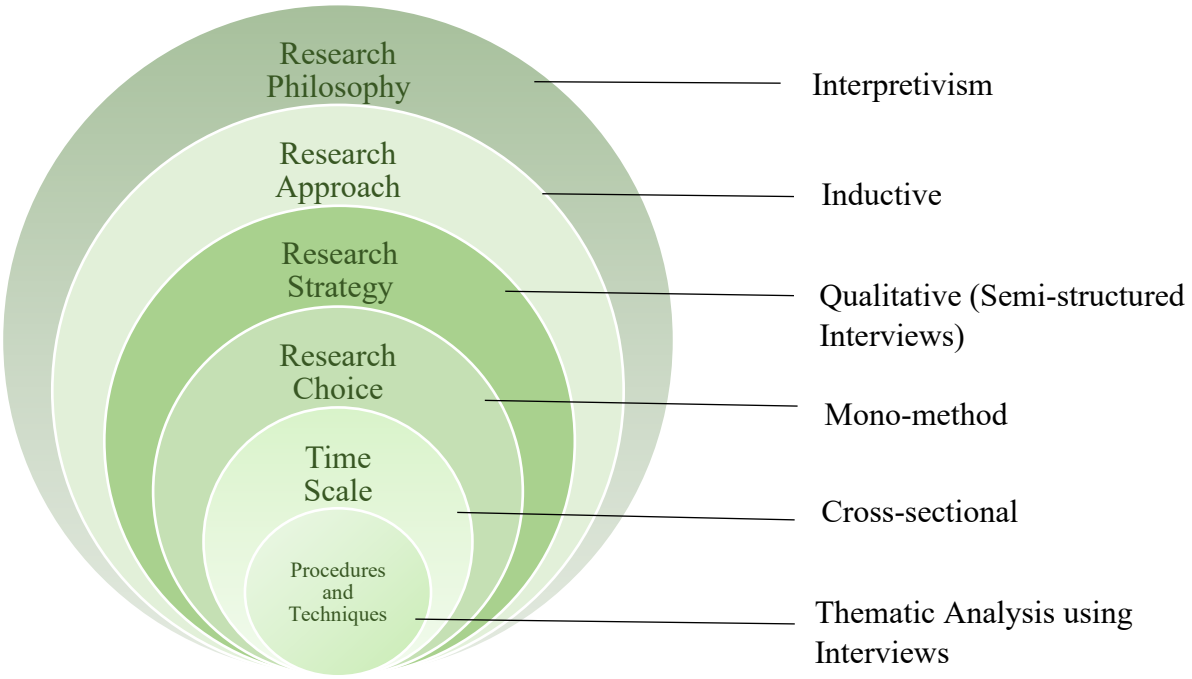


Figure 3-1: a) Original (source:(Penmypaper, 2023) and b)adapted Saunders onion(source: author)

3.2.3 Research Philosophy

The study uses an interpretive philosophy that states reality is socially constructed and should be interpreted from individuals lived experiences and meanings. Such a philosophy best fits qualitative research, which is undertaken to analyze multifaceted and dynamic phenomena such as the technological and regulatory atmosphere of Continuous Glucose Monitoring (CGM) systems. Interpretivism provides a meaningful understanding of stakeholders' experiences, particularly health care providers, regulators, and manufacturers of CGM(Junjie and Yingxin, 2022a).

Unlike positivism, which tries to quantify objective facts, interpretivism is receptive to subjectivity and context, focusing on how individuals construct reality in institutional and regulatory settings (Saunders *et al.*, 2023)This aligns with the use of semi-structured interviews and inductive reasoning, allowing the researcher to gather rich, nuanced data and build theory from it rather than testing existing hypotheses (Muzari *et al.*, 2022).

The interpretive strategy enables this research to ask how stakeholders perceive and respond to regulatory boundaries, ethical guidelines, and innovation pressures in the CGM industry.

3.2.4 Research Approach

This study employs an inductive research approach where theories and trends will be developed from the data, free from existing frameworks. Induction is best suited to exploratory research

with minimal existing theory, such as regulating AI-based Continuous Glucose Monitoring (CGM) systems. This approach allows for flexibility by remaining open to new ideas from participant perspectives. The inductive approach is aligned with the study's interpretivist philosophy and qualitative research approach, which aims to explore complex, context-dependent issues. It ensures that the findings are grounded in real stakeholder experience and can be applied to inform practical improvements in medical device regulation (Muzari *et al.*, 2022).

3.2.5 Research Strategy

The present study employs a qualitative approach, with semi-structured interviews and documentary analysis used to generate rich data. Semi-structured interviews offer room for guided but free-flowing conversation, whereby respondents can elaborate on factors like regulation compliance, creativity, and stakeholders' experiences in the use of CGM technology(Bell *et al.*, 2022). This ensures a balance between consistency of responses within interviews and potential for unearthing conclusions not previously suspected. Additionally, relevant regulatory reports, policy briefs, and industry publications will be analysed to contextualise stakeholder opinions and triangulate evidence. This is in keeping with the interpretivist worldview and allows the inductive process, whereby themes may emerge from real-world interactions and experiences rather than being preconceived a priori. It offers a thorough insight into the dynamic CGM regulatory landscape of Europe (Saunders *et al.*, 2023).

3.2.6 Justification for Methodology

The approach is designed to yield systematic and consistent data gathering and analysis. Employing a systematic approach minimizes bias and enhances the validity of results. Adopted methods align with the research objectives and adequately cover the key research questions. The data is gathered with the correct tools, while analytical techniques are selected based on their suitability for the data type and research purposes. This approach allows reproducibility, transparency, and consistency to guarantee that findings are credible and robust, thus making the study more reliable.

3.2.7 Research Timeline

The study was carried out over 14 weeks. The initial 2 weeks were spent developing research aims, getting ethical clearance, and agreeing on the methodology. Weeks 3 to 5 were spent carrying out a literature review. Data collection was done from weeks 6 to 9. Data analysis was

done in weeks 10 and 11. The dissertation write-up, revisions, and feedback were done in weeks 12 to 14, and the final submission was done in week 14.

3.3 RESEARCH METHODS

3.3.1 Data Collection Method

Semi-structured interviews were employed in this research as the primary data collection method. This qualitative method allowed for thoroughly exploring stakeholder experiences with regulatory concerns in CGM systems. Interviews were conducted face-to-face or remotely, depending on participant availability. The semi-structured format's flexibility ensured uniformity across essential points while allowing participants to offer additional information on specific areas of concern (Dovetail, 2023). This approach was particularly helpful in exposing the complex, context-specific character of compliance with EU MDR for CGMs (Muzari *et al.*, 2022).

3.3.2 Sampling Strategy

The purposive sampling method was utilised to access those with relevant CGM development and regulation expertise. Participants were selected according to their job position in regulatory bodies, CGM-producing companies, or healthcare centres. This method ensured the participation of expert respondents, thus improving the dependability and generalizability of the results (Lang and Nyimbili, 2024). The 10-12 participant sample was adequate to provide thematic saturation without compromising depth.

3.3.3 Techniques and Procedures

The interviews were taped with consent and analysed through transcription. Data confidentiality was ensured by anonymising the transcripts and storing all recordings per GDPR. The interviews were facilitated using open-ended questions that were flexible for arising issues, but still addressed key points by the research objectives (Muzari *et al.*, 2022). This facilitated rich, in-depth data best suited to thematic analysis.

3.3.4 Research Design Implementation

The interview guide was refined through interactions with the research supervisor. This iterative refinement process eliminated vague or biased wording in the question set, thereby enhancing data quality. Questions were on regulatory experience, technological issues, and stakeholder-suggested solutions to streamline compliance processes. The refined guide was a uniform tool for structured but exploratory interviews (Junjie and Yingxin, 2022a).

3.3.5 Interview Questions

The interview schedule was developed by combining the key themes of the literature review and cross-checking these against the key objectives of the study. Questions were posed to gather open, expansive discussions reflecting stakeholder perceptions on regulatory challenges, the integration of newer technologies such as artificial intelligence, and the general impact of compliance frameworks on innovation in CGM systems. The structure of the questions enabled exploratory discussion, which permitted the participants to reflect on both ideal practice and current practice. This allowed for the gathering of rich qualitative data to inform the thematic analysis of the study and achieve its main research aims (Mathieu *et al.*, 2024a).

3.4 PROTOCOLS BEFORE DATA COLLECTION

3.4.1 Ethical Approval

Griffith College Dublin's Ethics Committee formally approved the research proposal, interview framework, and consent process following a comprehensive evaluation. An information sheet explaining the purpose of the study, the ethical safeguards, and data handling practices was made available to the participants. This helped institutional ethics compliance and added the advantage of participant welfare during the entire research process.

3.4.2 Participant Recruitment

Participants were approached and identified through LinkedIn, professional networks, and regulatory bodies, thereby gaining access to individuals with experience in CGM technology and compliance. Purposive recruitment aimed at collecting balanced opinions from regulatory bodies, industry experts, and healthcare providers, thereby ensuring the validity of the research findings.

3.4.3 Informed Consent

Before participating, written or digital informed consent was sought. Participants were told that the study was voluntary, that they had a right to anonymity, and that they could withdraw at any time without incurring any negative consequences. It promoted transparency and upheld research ethics standards.

3.5 CONDUCT DURING DATA COLLECTION

3.5.1 Interview Procedures

Semi-structured interviews with 8-10 participants lasted approximately 30-45 minutes. Interviews were arranged on safe online platforms based on participants' convenience. Open-ended questions were applied to gather rich responses and enable participants to describe their experiences and perceptions. The researcher actively queried by asking for clarification and probing further where necessary. All interviews were recorded after permission had been obtained to provide an unbroken and precise record for transcription and analysis later.

3.5.2 Handling of Sensitive Data

All sensitive information gathered using interviews was processed per rigorous ethical guidelines and GDPR. Interview recordings and transcripts were kept safely in encrypted, password-protected folders only the researcher could access. Participant anonymity was ensured by removing personal identifiers from transcripts to keep all information confidential and used solely for research purposes.

3.6 PROTECTION OF DISSERTATION DATA

3.6.1 Data Storage and Security

All interview recordings and transcripts were stored on password-protected, encrypted servers with limited access to the researcher. Informed consent was obtained from all participants, detailing how the data would be used and stored securely. Participants were entitled to withdraw at any time without penalty. These measures ensured participant data were kept confidential and protected from unauthorised access by ethical research practice.

3.6.2 Anonymisation and Confidentiality

To guarantee participant confidentiality, names and identifiable information were removed at the transcription level. Pseudonyms were employed in reporting findings to double guard against identity breach. Direct participant contact was guaranteed to avoid third-party interference or confidential breaches. These arrangements were crucial in guaranteeing participant trust and adherence to research ethics.

3.6.3 Compliance with Data Protection Regulations

The study fully complied with the General Data Protection Regulation (GDPR) and institutional ethics standards. Data were stored for as long as necessary to perform analysis and

reporting before being permanently deleted. Before conducting interviews, an ethics application and declaration form were filled out and signed, and the study was conducted using best practices regarding data protection and participant confidentiality.

3.7 CONCLUSION

This chapter describes the research methodology for exploring regulatory matters and technological developments in Continuous Glucose Monitoring (CGM) systems. The research was guided by an interpretivist philosophy, recognising the value of subjective stakeholder experience, and took an inductive approach to allow theories to be generated from the data collected. A qualitative methodology, based on semi-structured interviews and supplemented by documentary analysis, was selected to create rich, detailed insights. Ethical approval was given, and stringent data protection protocols, informed consent, and anonymity of participants were maintained throughout the research process. The application of Saunders' Research Onion model provided a clear and systematic progression from philosophical assumptions through to practical data collection and analysis. In the main, the research approach used above ensures materiality, transparency, and credibility in ensuring this research impacts discussions around improving regulation and technology-driven innovation in the European CGM industry.

4 FINDINGS AND ANALYSIS

4.1 OVERVIEW

This dissertation analyses the concurrent dynamics of regulatory challenges and technological innovation in Continuous Glucose Monitoring (CGM) technologies. The study uses qualitative feedback from industry players to analyse how emerging technologies, such as AI integration, real-time data analysis, and wearable biosensors, influence CGM innovation. Simultaneously, it critiques the impact of the European Union Medical Device Regulation (EU MDR) on innovation, highlighting how reclassification, increased documentation, and delayed approval times undermine market responsiveness. Participants were apprehensive about a widening gap between innovation velocity and the rigidity of regulatory systems, particularly under the MDR. The research discovers a common thread: while safety remains the top priority, the regulatory burden now risks strangling technological innovation, especially in startups. The report highlights the importance of regulatory modernisation and strategic decision-making to bring CGM innovations to patients efficiently and safely without sacrificing compliance integrity.

4.2 PARTICIPANT PROFILE

Members were chosen according to their professional expertise in Continuous Glucose Monitoring (CGM) technologies, digital health innovation, and practical experience in EU Medical Device Regulation (MDR) compliance. Choosing ensured a variety of views from clinical, regulatory, and industry perspectives. A total of 10 members participated in the study, classified as follows:

• 2 Clinical clinicians (diabetes specialists or nurses) who deal with CGM technologies daily within hospital endocrinology units or outpatient diabetes care facilities.

• 3 Regulatory experts actively engaged in preparing regulatory documents, CE-marking dossiers, and coordination with notified bodies for EU MDR compliance of medical devices.

• 3 Manufacturing professionals in CGM system and digital health solution companies who belong to regulatory affairs or product development teams.

• 2 Legal experts with experience in medical device regulation, compliance, and intellectual property law related to digital health technologies.

All the participants provided insightful comments based on their professional experience, experience levels, and exposure to CGM implementation under EU MDR. Regulatory representatives emphasised documentation and compliance, whereas producers emphasised innovation constraints and lag in approvals. Clinicians offered practical inputs concerning CGM use, patient outcomes, and technology adoption challenges. Such diversity ensured a multi-dimensional view of how technological innovations and regulatory changes impact CGM deployment in the European market.

4.3 INTERVIEW DATA: THEMATIC ANALYSIS

Braun and Clarke's Method

The present research employed Braun and Clarke's six-step thematic analysis approach in analysing qualitative interview data among the stakeholders operating in Continuous Glucose Monitoring. Manual coding following complete immersion with data revealed recurring happenings which, at an early phase, were categorised under inclusive categories aligning with research focus topics. Themes were analysed and refined to be transparent and coherent, and each was defined and labelled with attention. Six prevailing themes were uncovered that reflected problems such as regulatory barriers, AI and software issues, cost and reimbursement, cybersecurity, SME access to markets, and stakeholder communication. Thematic analysis

enabled an unbiased process combining inductive and deductive logic to recognise areas of agreement, being aware of the unique perspectives of clinicians, regulators, and industry players. This process was beneficial for recognizing the overlap of emerging technologies with the complex regulatory environments, gaining insight into the broader issues facing the EU's CGM ecosystem(Konstantinos, 2024).

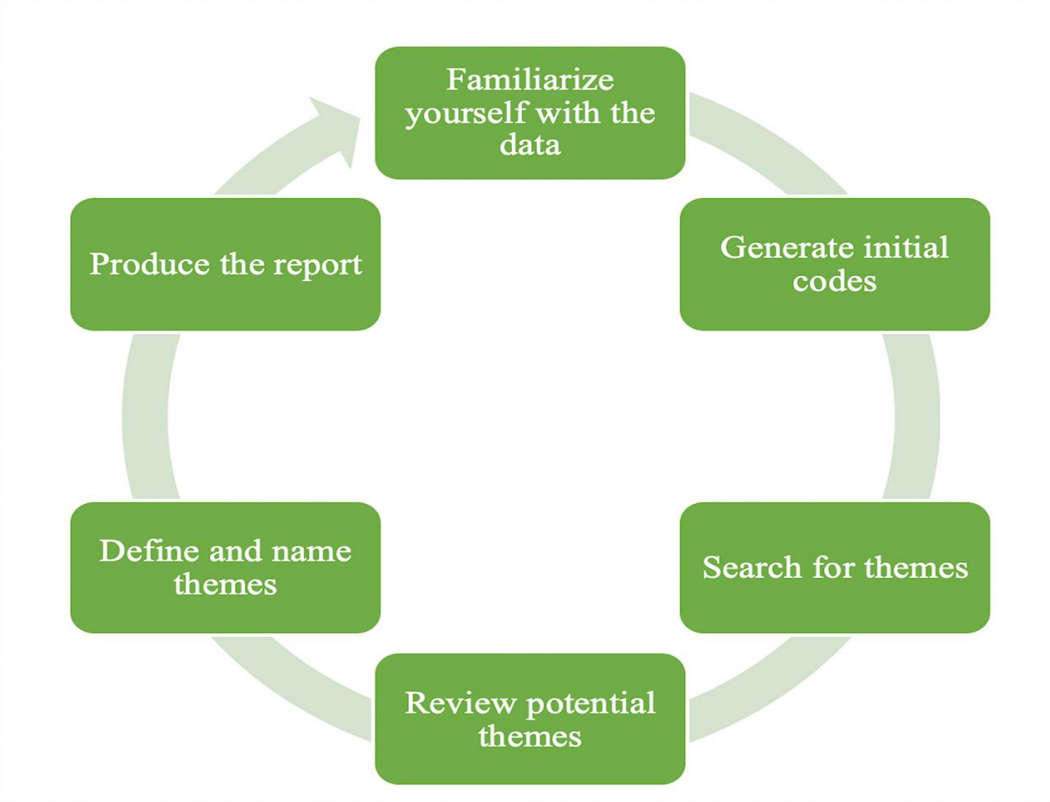


Figure 4-1Braun and Clarke's Method by (McLeod, 2024)

4.3.1 Advances in Sensor Design and Data Accuracy

Recent sensor design and data accuracy advances have significantly impacted the development of Continuous Glucose Monitoring (CGM) systems. Clinical, engineering, and user-experience interviewees highlighted how these advances drive adoption, enable clinical decision-making, and improve user satisfaction. The following sub-themes strongly emerged from the interviews.

The table reflects key advancements in continuous glucose monitoring (CGM) technology, including longer sensor wear duration, improved accuracy, and reduced calibration frequency. Participants identified greater convenience, comfort, and reliability, making it easier to integrate CGMs into daily routines.

Sub-theme	Description	Illustrative Quotes
Long-Wear, Low-Maintenance Sensors	Newer sensors last 14–21 days and require minimal handling.	"We now have sensors that last 14 to 21 days…" – Participant A
Reduced Calibration Needs	Most modern CGMs are factory-calibrated, reducing the need for finger pricks.	"With auto-calibrating sensors, it's more 'wear and forget'…" – Participant C
Enhanced Accuracy	Improved algorithms and sensor chemistry lower MARD values below 10%.	"Accuracy has closed the gap with traditional glucometers…" – Participant D
User Comfort and Discretion	Miniaturization and better adhesives reduce skin irritation and discomfort.	"Miniaturization has reduced discomfort…" – Participant B

Table 4-1 Advances in Sensor Design and Data Accuracy by researcher

1. Long-Wear, Low-Maintenance Sensors

Possibly the most well-publicised innovation has been the development of sensors with longer lifetimes. Some operate continuously for 14 or 21 days before being replaced, which is much better than the classic systems that called for more regular intervention. Please see below a quote from one of the participants.

"We now have sensors that last 14 to 21 days and don't need recalibration, which is a huge improvement for patients. They're less worried about daily maintenance, and that peace of mind is important." – **Participant A**

"We've minimized the hassle factor—users no longer dread sensor changeovers every few days." – **Participant D**

This increased durability not only reduces the user's fatigue but also proves cost-effective in the long term, making CGMs more viable for prolonged individual and clinical applications.

2. Reduced Calibration Need

Another significant advancement is eliminating or minimising the need for manual calibration. Previous devices required constant finger-stick checks to assure accuracy, often negating the benefit of a continuous monitor.

"Patients hated the constant need for finger pricks in older CGMs. With auto-calibrating sensors, it's more 'wear and forget'—they only need to act when alerts come in." – **Participant C**

Most participants pointed out that this convenience has greatly simplified CGMs, particularly for children, older patients, and those newly diagnosed with diabetes.

3. Enhanced Accuracy in Glucose Monitoring

Participants repeatedly emphasised the importance of improved data accuracy, mainly as patients and clinicians rely more heavily on CGM data for insulin dosing and lifestyle decisions.

"Accuracy has closed the gap with traditional glucometers. We're seeing Mean Absolute Relative Differences (MARDs) below 10%, which was unheard of a few years ago." – **Participant D.**

"Patients are making insulin dosing decisions based on CGM data. That speaks volumes about how much trust they place in the numbers." – **Participant E**

Improved sensor chemistry and advanced algorithms accounted for these gains, providing more real-time information and actionable data.

4. User Comfort and Discretion

Comfort and wearability were also cited as crucial aspects of CGM innovation. Thanks to miniaturisation and skin-friendly adhesives, patients now experience fewer irritations and discomforts.

"Miniaturisation has reduced discomfort, and newer adhesives are less irritating to the skin. This is crucial for kids or older adults with sensitive skin." – **Participant B.**

Discretion is another attribute linked to comfort. The more compact and body-conforming devices become, the less likely consumers feel embarrassed, reducing the stigmatisation of wearable medical devices.

4.3.2 Integration of Artificial Intelligence and Connectivity

Participating in consensus globally, Artificial Intelligence (AI) and connectivity during the digital age are revolutionising Continuous Glucose Monitoring (CGM) systems. The

integration of these technologies enables predictive analytics, seamless communication, and remote control, fundamentally changing diabetes care.

The image illustrates technology innovations in diabetes management using AI predictive analytics, mobile app integration, and remote monitoring. These advancements allow for early hypoglycemia prediction, real-time data updates via wearable technology, and the availability of shared data to patients, families, and clinicians.

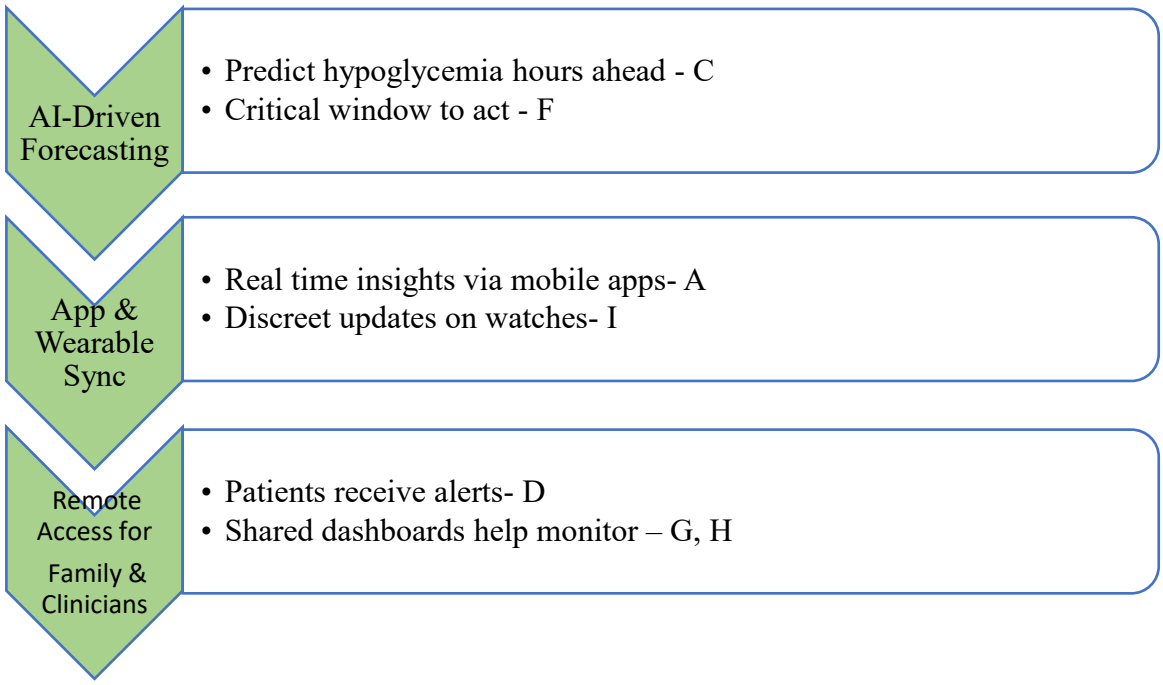


Figure 4-2Integration of Artificial Intelligence and Connectivity by the author

1. **AI-Powered Glucose Trend Predictions**

AI algorithms now allow CGMs to look back at historical glucose data and predict future trends, especially near hypoglycemic or hyperglycemic events about to occur. Such predictive capability changes care from reactive to proactive.

"With AI, we can predict hypoglycemia events hours before they happen—patients feel safer, and it allows timely action." – **Participant C**

Forecasting gives patients and clinicians a critical window to intervene, especially for high-risk cases." – **Participant F.**

Such a prediction improves physical results and relieves worry by giving caregivers and patients early warning systems.

2. **App-Based and Wearable Device Integration**

CGM devices are increasingly incorporated with smartwatches and smartphones, offering real-time notification, visualizations, and personalized insights.

"The app interface has become a game changer—patients can review trends, get advice, and even log meals and insulin." – **Participant A**

"People want discretion and speed. Notifications on smartwatches make data instant and less intrusive." – **Participant I**

The integration makes it easier and enables people to make lifestyle decisions based on always-updated information.

3. **Remote Access by Clinician and Family**

Connectivity functionality also provides family and clinicians with remote access to monitor glucose levels to allow timely intervention.

"Patients receive real-time alerts." – **Participant D**

"Remote dashboards let us monitor trends without needing the patient in the clinic." – **Participant G**

"This shared data strengthens the circle of care—it's collaborative." – **Participant E**

This distant accessibility provides better compliance, faster response, and better clinical judgment.

4.3.3 Regulatory Constraints Under EU MDR

The figure below is a word cloud generated from the participants' responses to regulatory constraints under EU MDR.

Figure 4-3 Word cloud for Regulatory Constraints Under EU MDR by the author

The participants expressed deep interest in the implications of the European Union Medical Device Regulation (EU MDR) on the release and innovation of Continuous Glucose Monitoring (CGM) devices. Since the MDR entered force in 2021, it has imposed more challenging classification requirements, documentation, and higher compliance burdens, particularly on sophisticated digital health technologies like CGMs.

1. **Reclassification to Higher Risk Classes**

CGMs, previously in less onerous categories, were relocated to Class IIb or III, which subjected them to more scrutiny and regulatory demands. Numerous respondents called the shift a key innovation point and an access barrier.

"*CGMs were moved to higher-risk classes under MDR. That means more paperwork, more evidence, more cost."* – **Participant E**

"Third-party audits and re-certifications are now mandatory even for minor upgrades." – **Participant A**

"It's no longer just about safety- it's about fulfilling bureaucratic checklists." **– Participant H**

2. **Greater Clinical Trial Requirements**

Participants said compliance today often requires extensive clinical data and robust post-market surveillance (PMS) strategies, which are especially burdensome for startups.

"Small manufacturers are now expected to provide large-scale clinical trial data, which they simply can't afford." - **Participant B.**

"*The compliance effort has doubled, maybe tripled, especially around risk documentation."* - **Participant I**

"*These expectations are not realistic for agile tech firms with limited funding."*- **Participant D**

3. **Cost and Time Implications**

Increased cost and longer approval times are posing serious barriers.

"*Some startups can't afford the process- it's pricing out innovation."* - **Participant F.**

"Even established companies are rethinking whether Europe is viable for launching new CGMs." - **Participant H**

"*Extended timelines also delay crucial access for patients."* - **Participant C**

Despite its aim to ensure safety and performance, participants were nearly unanimous in thinking that the MDR in its current form could kill innovation and market vibrancy in the CGM space.

4.3.4 Innovation Versus Compliance: A Strategic Trade-Off

Among the most critical issues raised by respondents was the increasing imbalance between the frenetic rate of technological innovation in Continuous Glucose Monitoring (CGM) systems and the slower pace of regulatory compliance. While safety standards remain supreme, most interviewees reported a painful trade-off between innovating at the boundaries and conforming to the strict regulatory requirements.

This illustration shows the compounding issues in medtech innovation caused by regulatory delays, legacy systems, and strategic trade-offs. There is delayed progress for firms as they struggle to balance limited resources between meeting complex compliance requirements and

innovation.

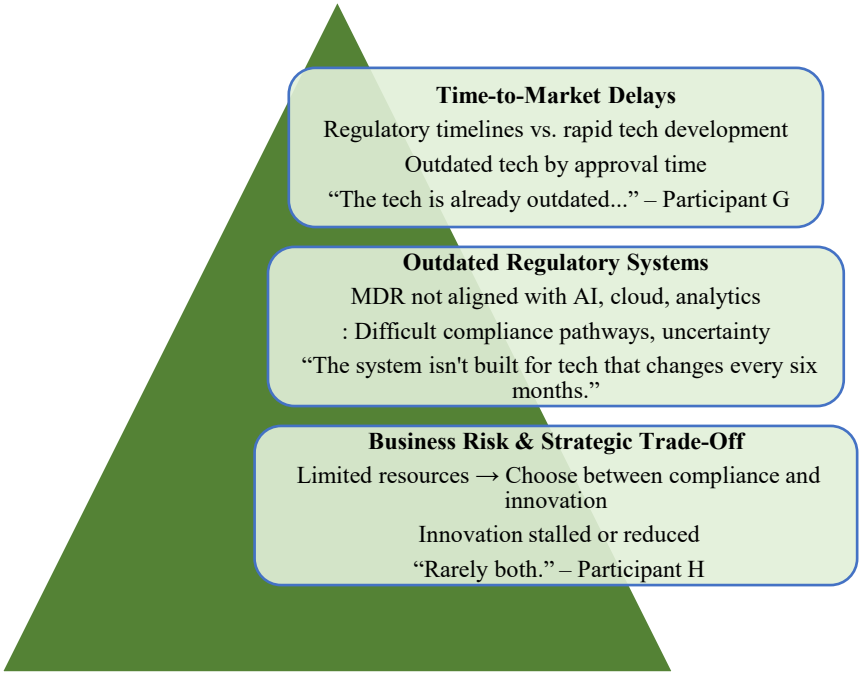


Figure 4-4 Innovation Versus Compliance: A Strategic Trade-Off by author

1. **Time-to-Market Delays**

Several participants discussed how regulatory timelines significantly delay the approval of new CGM technologies. **Participant G** described, *"By the time we finish clinical validation, the tech is already outdated. That's how slow the system is."* This delay creates a mismatch between development and delivery cycles, where developers invest in novel features that are quite possibly outdated and uncompetitive by the time approvals are received.

2. **Regulatory Systems Lagging Behind Technology**

The regulatory pathways, particularly under the EU MDR, were consistently described as outdated relative to modern medical technologies. Respondents described difficulty in identifying compliance pathways for AI, predictive analytics, or cloud-based data sharing innovations. As one respondent said, *"The current system just isn't built for technologies that change every six months. It's stuck in the past."* Such gaps often lead to protracted negotiations with regulators, which generate uncertainty and additional delays.

3. **Regulatory Navigation Business Risk**

Compliance with standards was highlighted by participants, especially those representing smaller firms. **Participant H** noted, *"Startups face tough choices- invest in innovation or meet regulatory costs. Rarely both."* This forces businesses to make strategic trade-offs, delaying development or decreasing the scope of their innovations to ensure regulatory approval is affordable within limited resources.

4.3.5 Balancing Regulation and Innovation

Several participants emphasised the urgent need to balance fostering innovation in Continuous Glucose Monitoring (CGM) systems and ensuring regulatory requirements for safety and efficacy are met. Rather than viewing regulation as an obstacle, many suggested proactive approaches that can better align innovation cycles and compliance processes.

1. **Pilot Zones for New Technologies**

One proposed solution presented was the introduction of regulatory sandboxes—regulated test beds in which new technologies could be tested under regulatory supervision without requiring full market approval. It would allow developers to obtain real-world evidence. At the same time, regulators observe performance and safety.

"*Regulatory sandboxes could let us test new CGMs under observation without full approval delays.*"- **Participant J**.

These areas would permit innovators to innovate quickly and responsibly before formal submission.

2. **Cross-Sector Collaboration**

Another theme that repeatedly came up was more collaboration between manufacturers, regulators, and clinical stakeholders. Participants desired a more formalised opportunity to engage with regulatory agencies early in development.

Participant I clarified, *"We need more open communication channels with regulators—before a device is even finalized."* This collaboration could match expectations initially, reducing costly revisions and confusion later in the approval process.

3. **Faster Feedback Loops from Regulators**

Participants also noted the need for more responsive and transparent regulatory feedback mechanisms. Delays in receiving comments or guidance can slow development and impact

time-to-market. One interview respondent suggested, *"A rolling review or phased feedback system would be a game changer- we could fix problems as we go instead of waiting months for feedback."*

Overall, participants demanded a more adaptive and supportive regulatory environment that still assures safety but does not stifle innovation with rigid timelines and a lack of specified requirements.

4.3.6 Barriers to Market Access and Mass Adoption

Despite Continuous Glucose Monitoring (CGM) 's technological maturity, stakeholders reported that systematic and pragmatic barriers hinder mass adoption. Although the benefits of CGMs are well-established, several barriers still restrict access, particularly in blended patient populations and healthcare settings.

1. **Inequitable Reimbursement Across EU Members**

Among the most common issues cited was the variation in insurance coverage and payment policy from region to region. Narrators explained how delay, denials, or prohibitively high out-of-pocket costs predictably kept CGMs out of reach for those who needed them most.

"My insurance wouldn't cover it initially. I had to wait almost a year and reapply through a different plan." - **Participant F.**

"The cost is too high for me without solid insurance. I want one, but it's unacceptable." - **Participant C.**

This incoherence of reimbursement schemes results in unequal access, particularly for patients in countries or regions with inadequate public financing of medical technologies.

2. **Resistance from Traditional Care Providers**

The second of these is clinician reluctance. Several of the participants reported instances in which healthcare professionals either ignored or dismissed CGM as an option, partly due to bias towards conventional finger-prick testing or unfamiliarity with technology.

"My doctor wasn't convinced I needed it. He said finger pricks were enough for now."- **Participant B.**

"I had to bring it up myself — they didn't even suggest CGM until I asked." - **Participant H**

This hesitation delays adoption and erodes patient confidence and trust in the treatments offered.

3. **Patient Concerns Over Complexity**

Users also mentioned user-related barriers, such as fear of continuous data monitoring, discomfort with wearable technology, or low digital literacy. Others were overwhelmed by the device's constant feedback.

"I'm not sure I want something stuck to me all the time. It feels invasive." - **Participant G**

"I worry it might make me more anxious, constantly seeing the numbers." - **Participant D.**

Others were unaware of the technology or lacked the support to access or properly utilise it.

"I didn't even know this technology existed until my friend mentioned it." - **Participant E.**

"I heard about it online, but nobody at the clinic explained how to get one." - **Participant A**

These results highlight the necessity of resolving individual and systemic barriers to enabling a more equal use of CGM across Europe.

4.4 COMPARATIVE ANALYSIS

The evolution of Continuous Glucose Monitoring (CGM) technologies, specifically in the EU regulatory environment, is a complex field where technological progress and regulation interact. The analysis below examines how findings of primary research interviews align with, vary from, or lack information developed in the secondary research literature review. Key themes include sensor technology development, AI and digital connectivity, regulation impacts, barriers to adoption, and solutions for balancing innovation and regulation.

4.4.1 Sensor Technology Advances and Accuracy

One of the most dominant themes from the primary research interviews is the revolutionary advancement of CGM sensor technology. Respondents repeatedly referred to improvements in wear duration, accuracy of sensors, calibration processes, and user comfort. For example, participants acknowledged the development of sensors that can be worn for 14 to 21 days, reducing how often they need to be replaced and minimising skin irritation. Also, reduced need for calibration- a trend toward factory-calibrated sensors- was cited as an essential user convenience and confidence enabler.

The existing body of literature fully substantiates these assertions, demonstrating that contemporary continuous glucose monitoring (CGM) systems, including the Dexcom G6 and the Abbott FreeStyle Libre 2, render finger-stick calibrations obsolete. The scholarly literature particularly focuses on Mean Absolute Relative Difference (MARD) levels less than 10%, reflecting enhanced accuracy, especially for hypoglycemia and hyperglycemia readings. Moreover, comfort-improving characteristics such as miniaturisation of devices, improvements in adhesive technology, and skin-compatible materials are emphasised in both data sets.

Whereas the concordance of the two information sources is evident, scholarly literature also discusses the clinical ramifications of such technological innovation. The studies referenced in the literature directly connect the upsurge in sensor accuracy, better Hba1c results, and the minimisation of diabetic complications; such a perspective is hardly mentioned during the primary research interviews. Although rich in qualitative narratives, the primary data lacks empirical measures and longitudinal data, which are prioritised in the literature.

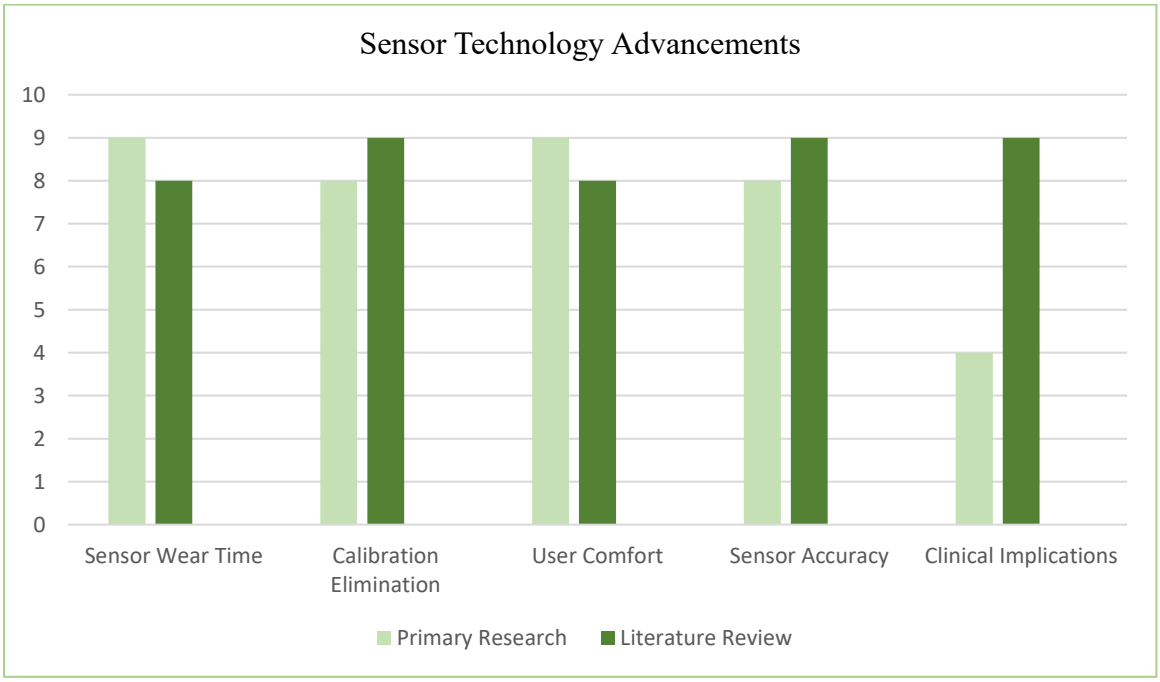


Figure 4-5 Sensor Technology Advances and Accuracy by author

4.4.2 Integration of AI, Machine Learning, and Digital Connectivity

Among the prevailing topics is the growing application of artificial intelligence (AI) and digital platforms in continuous glucose monitoring (CGM) devices. The study's lead authors focused on hypoglycemia prediction, real-time alerts, and compatibility with smartphones and smartwatches. These features enhance the user's independence in managing their health and enable preventive measures, particularly during sleeping hours or exercise time.

The literature review reinforces these technological trends by broadening the debate by putting Continuous Glucose Monitors (CGMs) into a broader mobile health (mHealth) perspective. The sources under examination demonstrate that CGMs now have artificial intelligence algorithms that provide pattern recognition and trend prediction, enhancing the early identification of complications. The literature also underscores the need for interoperability, particularly with insulin pumps, fitness trackers, and electronic health records (EHRs), which collectively create an integrated closed-loop system for diabetes management.

While primary and secondary data intersect in this topic, the literature supplies more regulatory depth. For instance, AI algorithms used in medical devices are more strictly regulated in the EU MDR due to their adaptive nature. This regulatory subtlety is not found in the primary interviews, which broadly discuss user-level upside without mentioning broader implications of regulating machine learning.

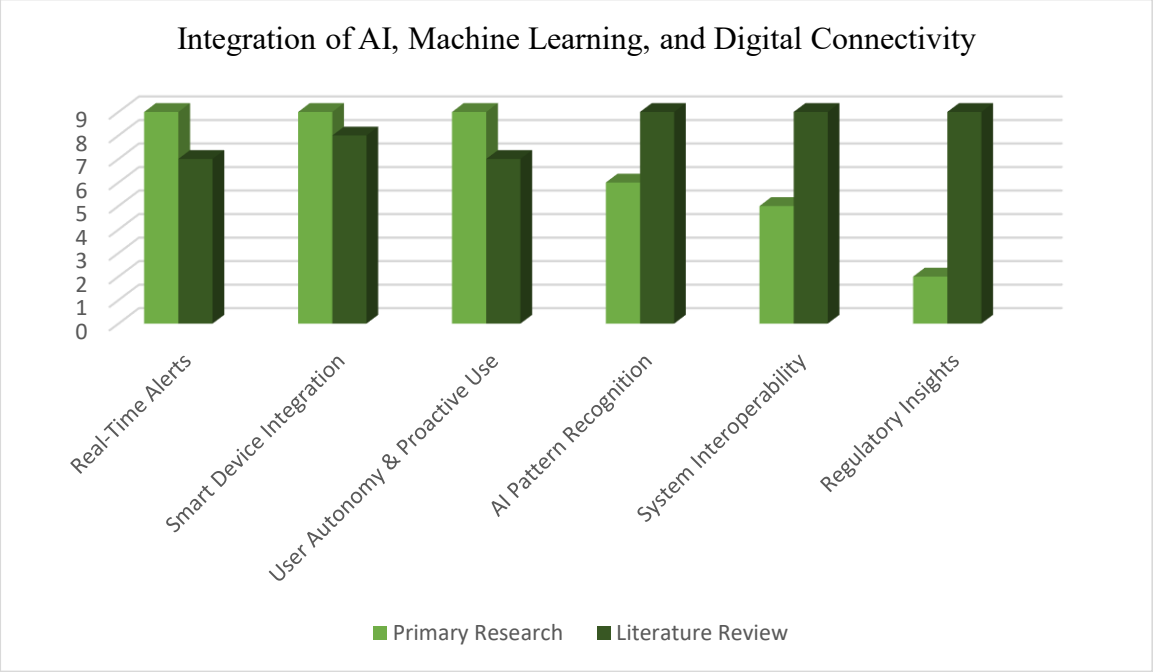


Figure 4-6 Integration of AI, Machine Learning, and Digital Connectivity by the author

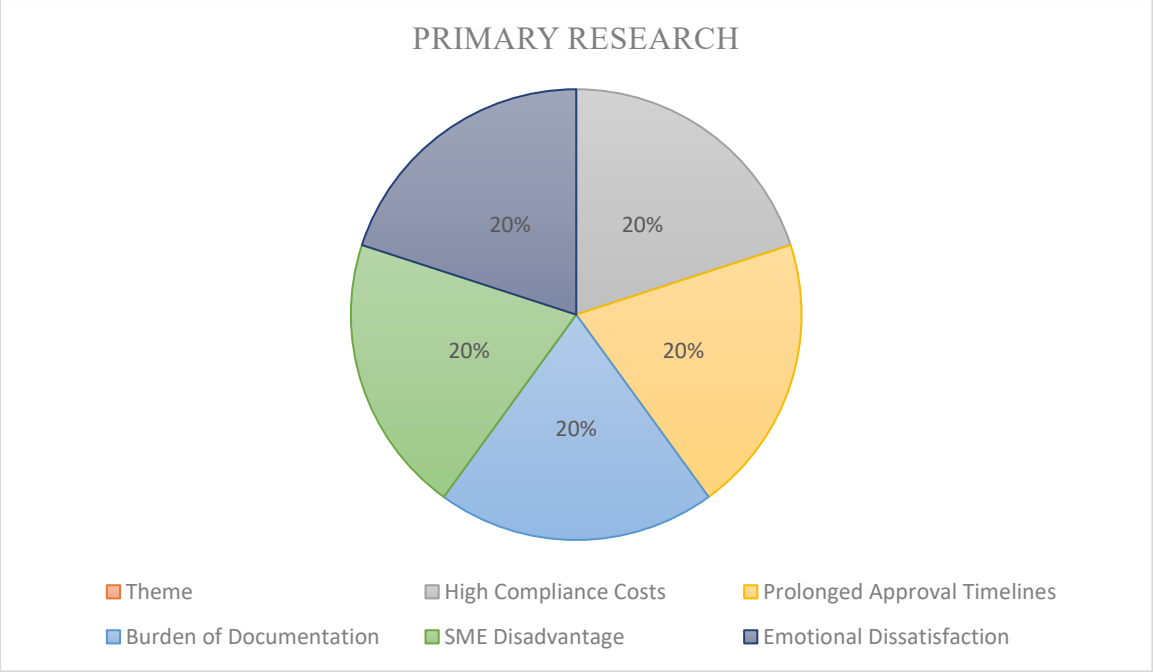
4.4.3 The Impact of EU Medical Device Regulation (MDR)

The impact of the EU Medical Device Regulation (MDR) on CGM innovation becomes a critical thread in the primary study and literature review. Interviewees from the industry and startup sectors were most vocal in their dissatisfaction with the MDR framework from the primary data. They emphasised that the regulation has created too many barriers to the market, increasing costs, long approval times, and lengthy documentation needs. One of the most significant problems was the reclassification of CGMs to Class IIb or III devices, which now

require greater levels of clinical proof and more frequent inspections, testing the capabilities of small companies.

Literature reviews endorse these conclusions but present them with a milder tone. Academic literature confirms that the MDR has placed greater regulatory demands on minimal and medium-scale enterprises (SMEs). Literature highlights the imbalance of resources available to SMEs compared to large businesses, as the former could have dedicated regulatory personnel, thus making compliance easy. Panic is evoked about the potential that it could dampen competition and thwart innovations.

However, one of the most significant differences between the two sources is how they construct the problem. The primary study constructs the MDR as a bureaucratic obstacle, playing along with stakeholders' working resentments. The literature does accept these challenges but prioritises regulatory firmness in ensuring patient safety and proper device function. This contrast draws out the classic tension: industry players value speed and price, with researchers highlighting ethical and safety trade-offs in public health policymaking.



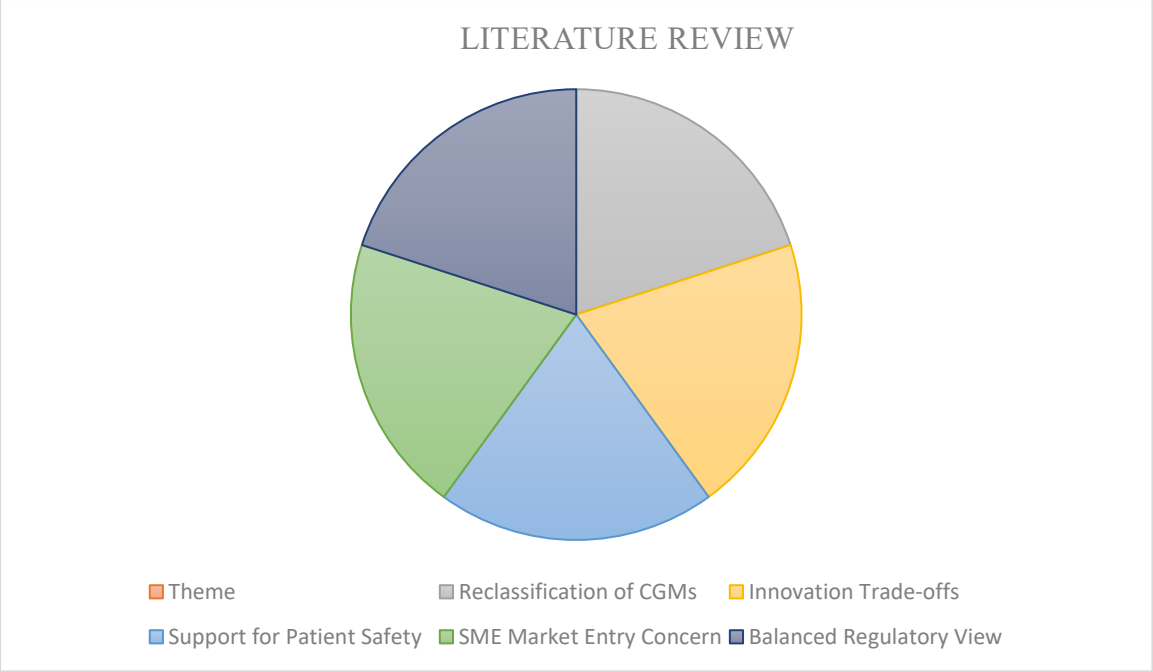


Figure 4-7 Impact of EU Medical Device Regulation (MDR) by the author

4.4.4 Innovation Versus Compliance: A Structural Tension

The issue of regulatory compliance vs. innovation arose as an omnipresent topic in the primary research and literature review. Interviewees repeatedly posited during primary data that regulatory delays are a problem that spans the technological innovation life cycle rather than stays within it, especially for AI-based CGM systems. The term "regulatory obsolescence" describes how products would become outdated when approved. Participants also criticised the EU MDR for its rigid structure, which was said to be more suitable for hardware than for fast-evolving software or AI systems. Proposed reforms were the establishment of regulatory sandboxes and early engagement tools to fill the gap between innovation and regulation.

The literature review reinforces these findings, repeating criticism of the MDR's rigidity. Scholarly sources take it further, proposing systematic overhauls in the guise of rolling reviews and sandboxed regimes, and taking lessons from the examples of international institutions like the FDA. This indicates a significant division: both sources recognise the problem, but literature offers concrete, actionable models of reform, while the main research dithers over conceptual ideas born out of frustration with the operation.

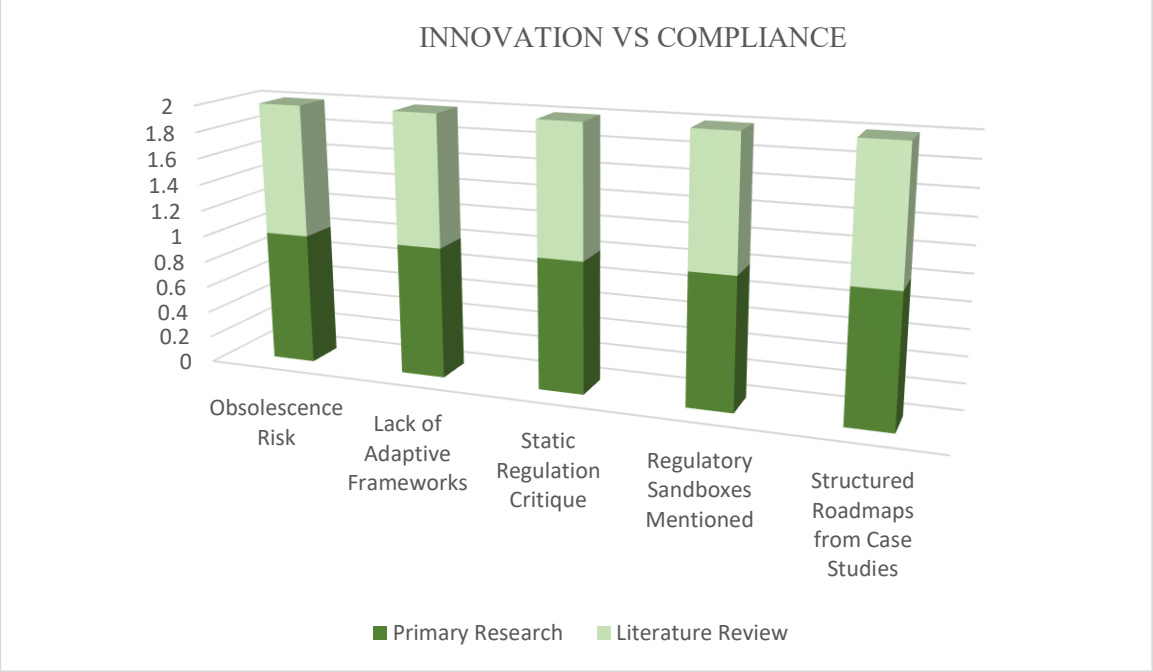


Figure 4-8 Innovation Versus Compliance: A Structural Tension by the author

4.4.5 Barriers to Adoption: Socioeconomic and Systemic Challenges

The adoption question for CGM is affected by systemic and individual barriers, as identified in the literature review and primary research. Up-front prohibitive costs, lack of insurance coverage, lack of physician support, and emotional obstacles like anxiety and device fatigue were all identified in primary interviews. Inadequate patient education and complicated interfaces were also identified as contributing to reluctance to adopt, especially for older or less health-literate individuals.

In comparison, the literature offers a broader view. It supports financial and emotional concerns but adds a structural and demographic component. For instance, access to CGM is extremely disparate by geography- individuals in rural areas or less affluent EU nations have reduced reimbursement rates and lower device availability. Additionally, the literature highlights the need for provider competence, noting that most general practitioners have received insufficient training in utilising CGM. Crucially, environmental sustainability, electronic waste, and data privacy issues- completely unmentioned in the interviews- are considered by academic sources, suggesting the complexity of adoption at more than just the user level.

This comparison reveals a mismatch: while primary data offers experiential, rich feedback, it overlooks the greater systemic inequalities and ethical concerns highlighted in secondary sources.

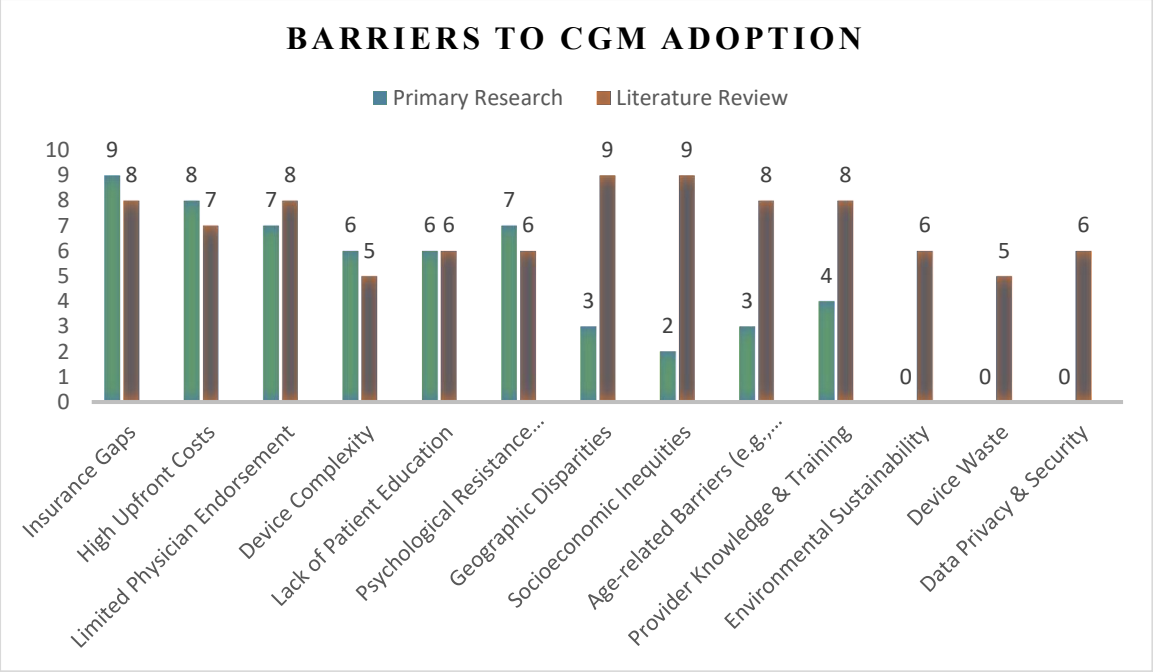


Figure 4-9 Barriers to Adoption: Socioeconomic and Systemic Challenges by the author

4.4.6 Strategies to Harmonise Innovation and Regulation

The Venn diagram graphically contrasts the findings of primary interviews and the Innovation and Regulation literature review.

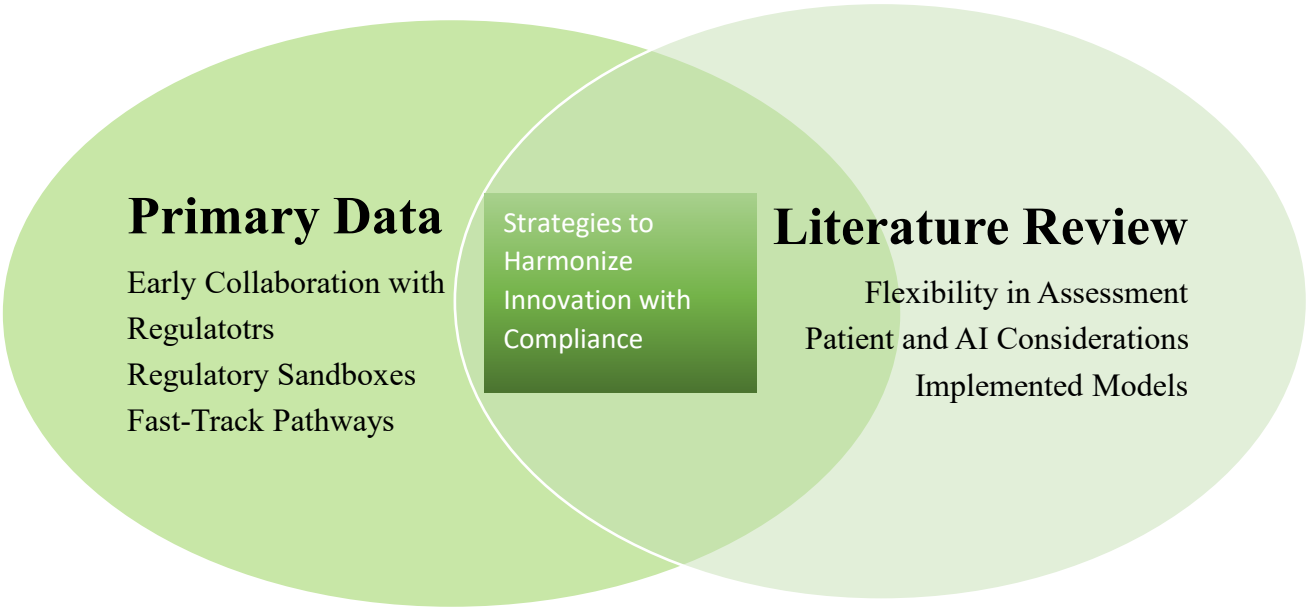


Figure 4-10 Strategies to Harmonise Innovation and Regulation by the author

The primary research and literature review underscore the importance of harmonising medical device innovation with regulatory regimes. Developer-friendly, practical solutions such as pre-emptive consultation with regulators, regulatory sandboxes for testing technologies, and accelerated approval pathways were suggested by interviewees to support innovation, particularly for SMEs and start-ups. These solutions aim to reduce delays and uncertainty in the regulatory process.

The literature affirms these ideas and discusses them based on concrete models. It speaks of the use of "living labs" and "iterative approval" procedures, which emphasise the utilisation of real-world evidence (RWE) and post-market surveillance to monitor over the long term for safety and performance. The literature further supports the formal inclusion of patient-reported outcomes (PROs) and customised guidelines for AI-based devices.

Divergence in detail: Writing often identifies strategies employed, e.g., the FDA's total product lifecycle strategy and the MHRA's digital health frameworks. Such explicit insight is absent in the primary data, reflecting a knowledge gap in strategic policy among stakeholders. Closing this gap may require more vision-led discussion between regulators and innovators so that policy keeps pace with technological progress.

4.5 SUMMARY TABLE

The table compares interviews and findings from the literature on issues like sensor technology, AI integration, regulation impact, and innovation inhibitors in healthcare. It shows high agreement on key matters but illustrates that the literature has greater policy richness and structural understanding, while interviews have richer user-oriented and experiential perspectives.

Theme	Primary Research (Interviews)	Secondary Research (Literature Review)	Comparison / Notes
Sensor Technology Advances & Accuracy	Emphasis on sensor longevity, factory calibration, and comfort improvements	Confirms accuracy (MARD <10%), clinical benefits (e.g., HbA1c improvement), material and design innovation	Strong alignment: literature adds clinical outcomes and empirical depth, missing from interviews
AI, Machine Learning & Digital Connectivity	Focus on usability: hypoglycemia alerts, smartphone sync, patient autonomy.	Broader mHealth context, trend prediction, EHR/insulin pump integration, regulatory challenges	Agreement in tech benefits; literature deeper in regulation and interoperability implications
Impact of EU MDR	Criticized as a bureaucratic burden, seen as slowing innovation, especially for SMEs	Confirms burden on SMEs; acknowledges rationale for stricter oversight and safety standards	Interviews are more negative; literature is more balanced, highlighting trade-offs between innovation and safety.
Innovation vs. Compliance Tension	Describes MDR as outdated, unsuitable for fast-evolving AI/software; calls for regulatory sandboxes	Suggests structured reforms (e.g., rolling reviews, sandboxing); references international best practices	Both recognize tension; literature offers detailed policy models, and primary data offers conceptual critiques.
Barriers to Adoption	Focus on personal/clinical hurdles: cost, insurance, device anxiety, complex UX.	Adds structural barriers: geographic inequality, provider training, environmental and data privacy issues	Literature paints a broader socio-technical picture; interviews focus on individual user-level challenges.
Harmonizing Innovation & Regulation	Proposes practical tools: pre-emptive consultations, regulatory sandboxes, fast-tracks	Discusses "living labs", RWE, PROs, global models (FDA, MHRA), lifecycle regulation	Shared goal: literature is more detailed in execution strategies,

			indicating a stakeholder knowledge gap

Figure 4-11 2 Summary Table of Primary Data vs Literature Review by the author

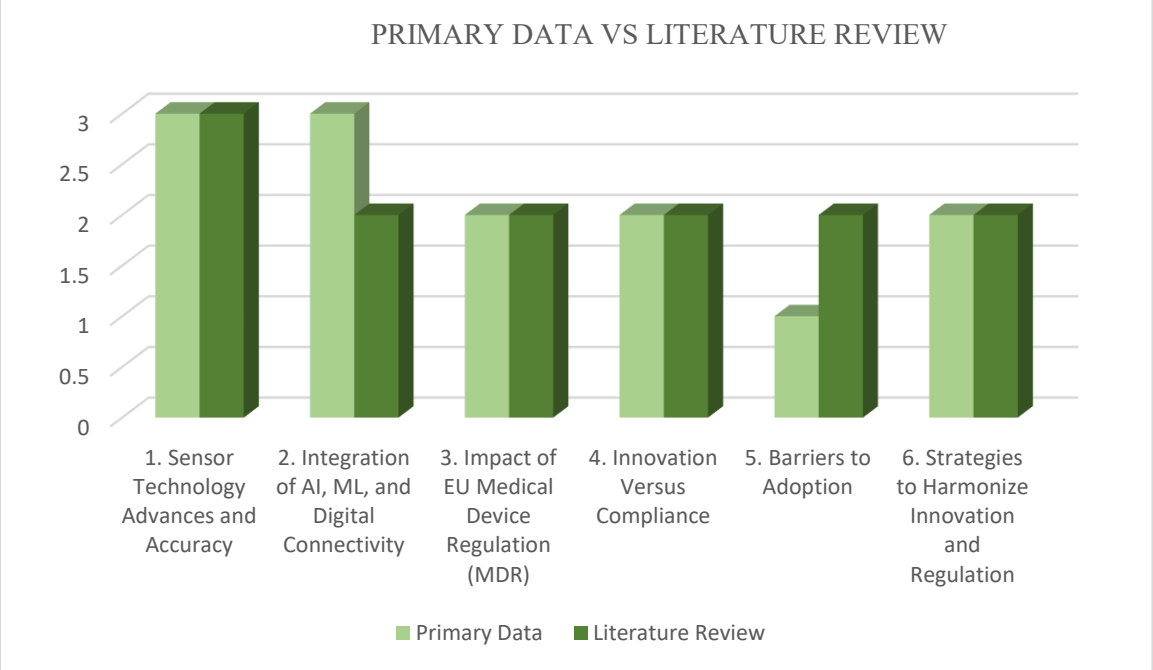


Figure 4-12 Primary Data vs Literature Review by the author

4.6 CONCLUSION

The findings of this study reveal a stark dichotomy between swift innovation in Continuous Glucose Monitoring (CGM) technologies and the stringent demands of regulatory frameworks, above all the EU MDR. While the technological development of CGMs is characterised by enhanced precision, size reduction, and AI-based data analysis, the developments are massively hindered by reclassification into higher-risk class device categories and complex approval pathways. The players again pointed out that such regulatory curbs not only increase the time and cost of reaching the market but could also render innovations obsolete before approval.

Most importantly, to small companies and startups, the cost-intensive aspects of compliance- e.g., the need for clinical trials, voluminous documentation, and third-party audits- put their existence at risk. Moreover, the lack of nimble regulatory channels for emerging technologies like predictive analytics or cloud-connected devices only adds to the burden. These barriers delay patient access to life-enhancing solutions and have a chilling effect on R&D investment.

Despite these challenges, however, the study also identifies areas of potential balance. Volunteers demanded more explicit guidance from regulatory bodies, more streamlined review processes for iterative updates, and more support for SMEs to navigate MDR provisions. The lesson is clear: A single-size-fits-all regulatory model is not appropriate to the fluidity of CGM innovation. Policymakers must collaborate with industry to co-produce adaptive, innovation-conducive regulation that guarantees safety without stunting advancement. This study lays the groundwork for the following studies on harmonising compliance with technological innovation for the ultimate benefit of innovators and the diabetic population.

5 CONCLUSION AND RECOMMENDATIONS

The findings of this research align closely with the existing literature, which recognises substantial technological advancements in Continuous Glucose Monitoring (CGM) systems. Both this research and the literature identify improvements in sensor accuracy, the integration of artificial intelligence, and greater connectivity as key factors driving improved diabetes management and patient outcomes. These innovations are consistently described as drivers of more effective, data-driven clinical decision-making.

Yet the results of this research diverge from previous studies by being less optimistic about the residual technical shortcomings of CGM systems. The results especially emphasize issues such as the limited life span of sensors, the difficulty of calibration, and user interface-related challenges, which are played down or ignored in previous literature, which is generally preoccupied with the advantages of technological progress.

Regarding regulation, the literature and the findings acknowledge the European Union Medical Device Regulation (EU MDR) as a seminal framework that influences the uptake of Continuous Glucose Monitoring (CGM) systems. The findings, however, provide a deeper understanding of how the complexities of regulation lead to delayed product approvals and create challenges for small and medium-sized enterprises (SMEs). In contrast, the literature generally sees regulation as a static context instead of an adaptive challenge.

Moreover, the results explicitly integrate the views of various stakeholders such as clinicians, developers, and manufacturers. The integration provides deeper insights into the regulatory compliance issue of balancing adherence to rules and rapid innovation advances- a consideration not well explored in prior research. Finally, the results provide prescriptive

recommendations on balancing regulatory guidelines with technological advances, thus fulfilling a gap in the literature of separately addressing innovation and regulation.

5.1 SUMMARY OF MAIN FINDINGS AND THEIR IMPLICATIONS

5.1.1 Technological Breakthroughs

Wearable health technologies have grown exponentially, particularly in sensor miniaturisation and precision. Such growth, accompanied by integrating Artificial Intelligence (AI), Internet of Things (IoT), and mobile connectivity, has transformed device functionality. Innovations today support real-time monitoring, data analysis, and cloud storage, all made available on smartphones. These abilities have facilitated device use and patient engagement, improving clinical outcomes and higher adoption. The convergence of bioengineering and digital health has led to more individualised and anticipatory care, making these devices indispensable in preventing and managing chronic disease.

5.1.2 Regulatory Challenges

This quick innovation is juxtaposed against a backdrop of ever-more advanced regulatory environments. The Medical Device Regulation (MDR) has brought stringent clinical verification and post-market surveillance requirements in the European Union. The reforms demand mass documentation, greater scrutiny, and longer approval periods. To SMEs and startups, these barriers often become unbalanced costs and resource commitment, potentially stifling innovation at an early stage. Lack of streamlined procedures and a one-size-fits-all approach to regulation contribute to navigating compliance channels.

5.1.3 Balancing Innovation and Compliance

The natural tension between rapid technological innovation and demands for safety and effectiveness is a delicate balancing act. Regulatory mechanisms ensure product quality and patient safety in one respect, but overly burdensome systems can deny timely access to innovative treatments in another. Regulatory risk and inconsistent regional requirements burden companies requiring global market access, deterring cross-border innovation.

5.1.4 Proposed Solutions

To address such challenges, the stakeholders demand flexible regulatory systems that remain abreast of technological progress. Recommendations encompass harmonising international guidelines, enhancing documentation quality in requirements, and creating regulatory sandboxes to test innovations in a secure environment. Preliminary collaboration among

developers and regulators is essential to circumvent compliance traps and align expectations. These practices aim to drive innovation without compromising on safety and effectiveness.

5.2 SUMMARY OF DIFFERENCES BETWEEN FINDINGS AND LITERATURE

This study generally concurs with existing literature highlighting significant technological advances in Continuous Glucose Monitoring (CGM) systems, including improved sensor accuracy, the addition of Artificial Intelligence (AI), and real-time data transmission. The sources both identify these improvements as a revolution in the care of diabetes and the quality of life in patients. However, the findings augment the argument by pointing out recurring technical limitations, such as sensors' limited lifespan and the user interface's complexity, typically underreported in studies that focus primarily on technological innovation's benefits.

Whereas the literature habitually places the European Union Medical Device Regulation (EU MDR) as a watershed but static policy landscape, this study's findings locate it as an agential barrier to innovation, most particularly for startups and small-to-medium-sized enterprises (SMEs). Interviewees emphasized the burdens of higher documentation, reclassification, and longer approval times as direct, linear barriers to product development and access to market.

Furthermore, the findings are a more extended reflection on stakeholder opinion, specifically developers' and clinicians' views, on this ongoing tension between remaining compliant and the need for innovation at speed. Contrary to the literature that seeks to separate regulatory analysis from technological development, the research brings these together and illustrates the need for strategic consistency. The participants called for more adaptable regulatory models and active engagement between regulators and innovators. In this way, this research is answering a fundamental gap in the literature: the absence of a wide-ranging framework that considers at once regulatory constraints and technological patterns to encourage CGM innovation.

5.3 RECOMMENDATIONS

Based on the study's findings, several practical and academic recommendations are made to address the complex nexus between technological innovation and regulatory oversight in Continuous Glucose Monitoring (CGM) systems. Practically, regulatory agencies are recommended to employ more flexible, innovation-friendly frameworks such as phased or conditional approvals. These frameworks have the potential to enable faster time-to-market for CGM devices without compromising on stringent safety expectations. Greater communication between developers and regulators, particularly at the earlier phases of development, would

reduce uncertainty and enhance understanding of each other's expectations- a shift beneficial to resource-constrained startups. Additionally, targeted educational initiatives for developers regarding regulatory pathways, especially AI and data-sharing capabilities, can prevent compliance mistakes and foster more streamlined innovation cycles. Further, regulatory harmonisation across regions would streamline device approvals, prevent duplication, and ease international market entry.

Academically, this study recognises a need for larger, multi-stakeholder research encapsulating the perceptions of regulators, developers, clinicians, and patients. The subsequent studies must cover how regulation affects innovation ecosystems rather than treating sectors in isolation. Comparative analyses of regulatory regimes- e.g., between the European Union's MDR and the FDA pathways in the United States- would be a source of best practices and adaptable models. As AI becomes more central to CGM operation, targeted research on the regulatory specifics of algorithmic devices is needed. Lastly, empirical studies of how specific regulatory mechanisms affect actual innovation results in the real world will be critical to informing adaptive, evidence-based policy making in digital health.

5.4 LIMITATIONS AND CONTRIBUTIONS OF THE RESEARCH

5.4.1 Limitations

This study, as rich as it is in insights into the regulation-technology nexus in Continuous Glucose Monitoring (CGM) systems, has limitations. Firstly, the representation of stakeholders in the study is relatively narrow, with the principal stakeholders being developers, clinicians, and regulatory specialists. This means that other significant stakeholders, particularly patients, caregivers, and small-scale innovators, have minimal representation. Their omission may leave the study with some limitations in comprehensiveness, particularly in identifying user-level barriers to the uptake of CGM or non-formal workarounds in small organisations.

Second, most analyses rely on document-based secondary data, including regulation texts and literature, rather than extensive primary data collection. While interview insights add depth, the number of samples is small, which could restrict the variety of experiential accounts. Third, the study's concentration on the European Union Medical Device Regulation (EU MDR) restricts the worldwide applicability of the findings. Regulatory dynamics in other geographies, such as those regulated by the U.S. Food and Drug Administration (FDA) or developing countries, may pose single-use challenges or opportunities not covered here. Finally, with the

fast pace of AI and digital health evolution, findings based on current regulations will be overtaken as emerging frameworks and technologies emerge.

5.4.2 Contributions

Despite its constraints, this study has several significant contributions. It provides a focused analysis of the dynamic between technological innovation and regulatory compliance within CGMs- a largely unexplored area in academic scholarship. In outlining specific regulatory challenges introduced by the EU MDR, especially for small and medium-sized enterprises (SMEs), the research provides a valuable basis for future regulatory reform discussions. It also recommends specific steps for better coordination between innovation and compliance, such as regulatory sandboxes and early-stage engagement between developers and regulators. Significantly, the study precedes stakeholder-driven input, revealing real-world implementation challenges typically not considered in top-down policy debates. The findings inform academic discourse and offer actionable implications for policymakers, developers, and healthcare practitioners.

5.5 SUGGESTIONS FOR FUTURE RESEARCHERS

Future studies should also examine the intersection of technological advancement and regulatory unification in Continuous Glucose Monitoring (CGM) systems. Some areas that should be enhanced include sensor reliability improvement, calibration problem solving, data exchangeability improvement, and transparency and interpretability enhancement of AI algorithms. User interface usability studies and device consistency would help facilitate patient trustworthiness, acceptability, and long-term use of CGM technologies.

Comparative analyses among regulatory regimes- e.g., the EU's MDR, the U.S. FDA system, and the new Asian markets- would be informative regarding how different policy environments and healthcare infrastructures affect innovation pathways and time-to-market outcomes. Such analyses could determine best practices that balance technological flexibility with rigorous safety regulation.

In addition, more advanced clinical studies need to be carried out to assess the impact of CGM use on patient outcomes. Long-term glucose control, complication prevention, and quality-of-life improvement studies would strengthen the argument for increased use of CGM. In future analyses, considering patient, caregiver, and public health practitioner perspectives would enrich the assessment of real-world benefits and access barriers.

Finally, a longitudinal examination of how CGM technologies evolve in response to regulatory shifts would provide crucial insight into the dynamic policymaker-innovator feedback loop, making more adaptive governance in the digital health sphere possible.

5.6 FINAL REFLECTION

Completing this dissertation has been mentally challenging and gratifying, giving a complete picture of the complementary relationship between the regulatory framework and technological progress in the Continuous Glucose Monitoring (CGM) industry. Through close examination of both cutting-edge technologies and broader regulatory constraints, I have developed a more advanced understanding of how health technologies evolve- and of the difficulties inherent in bringing them safely and effectively to market.

This research has significantly developed my critical and analytical capacities, notably in integrating diverse stakeholder opinions, interpreting policy meanings, and analysing technological advancements in healthcare. It has also made me more aware of the need for proportionate regulation to achieve innovation and guarantee patient safety and public trust.

In the process, I was most impressed by the intersection of public policy and health tech. Understanding the challenges regulators, clinicians, and developers encounter has given me the drive to be involved in solutions that deliver timely and responsible innovation. I am now sufficiently equipped to take on future work in bridging responsiveness in regulation and technological advancement in the medical tech sector.

The dissertation has enriched my academic knowledge and impacted my long-term career aspirations. The knowledge gained will continue to shape my subsequent academic research and professional practice in the fast-evolving digital health environment. I look forward to applying this learning in fostering inclusive, safe, and scalable innovation in healthcare technologies.

Additionally, I would like to mention the usage of AI apps like ChatGPT and Grammarly for doing this dissertation for refining the title, making the figures and correcting the grammatical errors.

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7 APPENDICES

7.1 APPENDIX 1: ETHICS FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor.

RESEARCHER'S NAME: ROSE MARIYA SHAJU

PROGRAMME OF STUDY: MSc. MEDICAL DEVICE TECHNOLOGY AND BUSINESS

SUPERVISOR'S NAME: MINA GHAHREMANZAMANEH

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

For Student:

STUDENT SIGNATURE: Rose Mariya

DATE: 20/03/2025

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ■

SUPERVISOR SIGNATURE:

DATE:28/03/2025

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

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

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

Continuous Glucose Monitoring (CGM) has significantly transformed diabetes management by monitoring glucose levels in real-time, reducing reliance on the traditional fingerstick test, and improving glycemic control. Despite this, the regulatory frameworks governing the application of CGM devices, particularly in the European Union, create intimidating

challenges for both producers and clinicians. The European Medical Device Regulation (MDR) sets compliance standards, but there are concerns regarding how well it promotes the accuracy, performance, and safety of CGMs, especially with artificial intelligence (AI) and sophisticated biosensors being incorporated.

This research aims to evaluate regulatory barriers and technological innovation in CGM systems and consider how they affect market adoption and innovation. It will examine the impact of conformity specifications on product development, outline loopholes in existing regulating systems, and suggest steps towards the synchronization of regulations and innovation.

TITLE

Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor.

AIM

To investigate the regulatory challenges and technological advancements in Continuous Glucose Monitoring (CGM) systems, analyze their implications for market adoption, and propose solutions to balance innovation with regulatory compliance.

OBJECTIVES

1. To investigate recent technological advancements in CGMs, including sensors, AI, and connectivity.
2. To examine the EU's MDR controlling CGMs.
3. To identify challenges in balancing innovation with regulatory compliance.
4. To propose strategies to harmonize innovation with regulatory standards.

1.2 Research methodology

This study employs a qualitative study design, and semi-structured interviews with the major stakeholders, including regulatory experts, CGM manufacturers, healthcare professionals, and policymakers. Thematic analysis will be employed to investigate the technological and regulatory landscape of CGMs.

Data Analysis

- Thematic analysis will be used to analyze interview transcripts, pulling out key trends and themes in relation to regulatory challenges, compliance actions, and technology developments.
- NVivo computer software will be used to structure qualitative data, facilitating systematic coding and comparison of expert opinion.

Ethical Considerations

- Informed consent will be requested from participants.
- Confidentiality and data anonymity will be ensured.
- Participants have the right to withdraw at any time without penalty.

By integrating expert knowledge with up-to-date research, this project will give a comprehensive insight into the regulatory framework for CGM devices and help facilitate the continuation of discussion on the areas of innovation and compliance in diabetes technology.

Data Collection Methods

Expert Interviews:

- Individual interviews with 10-12 stakeholders were selected based on their particular areas of expertise in CGM technology, medical device legislation, and medical use.
- The interviews will be conducted online (via Zoom or Microsoft Teams) depending on the participants' preference.
- A semi-structured method will be used to allow flexibility in following up on emerging themes without losing coherence with research objectives.

SECTION 2: POSSIBLE ETHICAL ISSUES

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

SUBJECT MATTER

Does the research proposal involve:

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

RESEARCH PROCEDURES

Does the research proposal involve:

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

PARTICIPANTS

Does the research proposal involve:

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

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

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

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

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

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

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

SECTION 4: ABOUT YOUR PARTICIPANTS

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

Sample size 10-12 participants

- Regulatory experts and policymakers – 2 participants
- Manufacturers: Companies or developers of CGM devices. – 3 participants
- Healthcare professionals: doctors, endocrinologists, diabetes specialists – 2 participants • Legal experts specializing in medical device regulation- 3 participants

Regulatory Experts and Policymakers (2): These members are experts in medical device policy and regulation, providing insight into regulatory systems, approval processes, and evolving legislation impacting CGM devices.

Manufacturers (3): Specialists in companies that develop, design, or distribute CGM devices and offer advice on product development, market, and regulatory concerns.

Healthcare Practitioners (2): Doctors, endocrinologists, or diabetes specialists with handson experience with CGM devices, providing first-hand knowledge of device performance, patient results, and clinical use.

Legal Experts (3): Legal professionals with expertise in medical device regulation, intellectual property, and compliance, advising legal matters related to device development and market entry.

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

LinkedIn and Professional Associations:

Utilizing LinkedIn to connect with regulatory affairs professionals, CGM manufacturers, and healthcare professionals.

For professional guidance, engage with professional organizations such as the Regulatory Affairs Professionals Society (RAPS) and medical device regulatory agencies.

Institutional and Organizational Outreach:

Reaching out to universities and research institutions engaged in CGM and diabetes technology research to get in touch with researchers and developers.

Reaching out to hospitals, clinics, and healthcare organizations that use CGM technology to engage with clinicians and diabetes specialists.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

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

Please confirm below that your information letter covers:

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

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

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

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

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.
No: my research study involves an online survey only and/or does not require signed consent

SECTION 6: STORAGE OF DATA

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

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

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

•All the research data such as interview transcripts, audio files, and analysis reports will be kept safely on password-protected devices and safe cloud storage.

•Data will be kept for 1.5 to 2 years from the end of the study as per academic standards after which it will be deleted safely.

•Access will be restricted to the researcher and supervisors alone to maintain the confidentiality of the data.

•Information protection will be ethically institutional and GDPR compliant, ensuring participant anonymity and confidentiality.

•Identifiable personal data will be anonymized or redacted to safeguard participant identities.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

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

Yes No✓

7.2 **Student consent**

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

Yes No✓

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

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

SECTION 9: DOCUMENT CHECKLIST

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

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

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

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

For Student:

STUDENT SIGNATURE: Rose Mariya

DATE: 20/03/2025

7.2 APPENDIX 2: CONSENT FORM

CONSENT TO TAKE PART IN RESEARCH

GRIFFITH COLLEGE

Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor

- I *(insert participant name*) voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study

- I understand that participation involves a questionnaire interview related to Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor.
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research, my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview that may reveal my identity or the identity of people I speak about.
- If the interview is carried out virtually, I agree to my interview being audio-recorded
- I understand that disguised extracts from my interview may be quoted in dissertations, conference presentations, published papers, library.
- If data is coming from within one company or specifically about one company. I understand that I will adhere to all of the codes of conduct and employee confidentiality about my organization and there is no expectation to breach these by partaking in this research".
- I understand that if I inform the researcher that I or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be securely stored on their device, protected by a security password, for two years. Access to this data will be restricted to authorized individuals as necessary.
- I understand that a transcript of my interview, with all identifying details removed, will be kept for grading the dissertation.
- I understand that under freedom of information legalization, I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name- ROSE MARIYA SHAJU

Degree Programme- MSC MEDICAL DEVICE TECHNOLOGY AND BUSINESS

College Details- GRIFFITH COLLEGE DUBLIN

Contact number- 0892135878

Contact mail- rosemariya.shaju@student.griffith.ie

Signature of participant

[Full Name – Printed]

Signature of research participant

---------- ---------- Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

---------- ---------- Date

Signature of researcher

7.3 APPENDIX 3: PARTICIPANT INFORMATION LETTER

Participant Information Letter

Evaluating Regulatory Challenges and Technological Breakthroughs in Continuous Glucose Monitor.

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

I am Rose Mariya Shaju, a postgraduate student pursuing an MSc in Medical Device Technology and Business at Griffith College Dublin. This research, as a part of my dissertation, examines regulatory challenges and technological advancements in Continuous Glucose Monitoring (CGM) devices. CGMs improve diabetes care, but complying with the European Medical Device Regulation (MDR) is demanding, especially with AI-based technology. In this research, regulatory barriers, market adoption issues, and compliance strategies will be assessed to provide stakeholders with insight. The results will contribute to the argument for medical device regulation and innovation, finding a harmonious balance between technological development and patient safety.

WHAT WOULD BE TAKING PART INVOLVED?

Participation in this research involves a one-to-one semi-structured interview lasting approximately 30-40 minutes. The discussion will be centered on regulations on CGM, technological advancements, and industry challenges. With your permission, audio recordings of interviews will take place to guarantee good transcription and analysis. Participants' anonymity will be maintained, and participants may withdraw from participation at any time. The research will strive to secure expert views while keeping to a minimum the disruption caused.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to participate in this study because of your experience working in the field of Continuous Glucose Monitoring (CGM) technology, medical device policy, or clinical practice. As a policymaker, regulatory authority, CGM industry representative, or healthcare provider, your experience is valuable in understanding challenges and innovation in CGM devices. You were selected from professional networks, industry associations, and institutional contacts as someone with valuable experience to contribute to this study.

DO YOU HAVE TO TAKE PART?

Participation in this study is entirely voluntary. You have the right to decline participation, skip any questions you do not wish to answer, or withdraw from the study at any time without any consequences. Your decision to participate or cancel will not affect your professional standing or relationship with the researcher.

Please note

- That participation is voluntary.
- that a decision not to consent will have no adverse consequences.
- that consent can be withdrawn at any time

If you wish to withdraw, don't hesitate to get in touch with me at 0892135878 or by email at rosemariya.shaju@student.griffith.ie. Your data will be removed upon request.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

There are no foreseen risks to taking part in this research. The rest of this section is good. The research value is to contribute to regulatory discussions that have the potential to enhance CGM innovation and patient safety. In the event of any problem, participants can withdraw at any time and all the information will be kept confidential.

WILL TAKING PART BE CONFIDENTIAL?

All information to be published will be kept confidential and anonymised. The final report will not include titles, names, or any other identifying features, and all information will be stored securely in accordance with GDPR requirements. Audio files and signed consent forms will be securely stored for research authentication but not published publicly. Confidential business information will be utilized only once permission is sought in advance.

Confidentiality may only be broken if there is a significant threat of injury to the participant or others, for example, in respect of abuse, self-harm, suicidal thoughts, or criminal activity. Action in these situations can be taken appropriately. Participants can withdraw at any time without sanction, and data will be irretrievably destroyed at request. These practices maintain participant privacy and data security throughout the study.

HOW WILL THE INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms and original audio recordings will be stored safely in a password-protected file on a restricted-access university server until the award of my degree. Only my supervisor and I will have access to this data. A fully anonymised transcript of an interview

will be kept for two years from the date my degree is awarded, with all identifying information removed. All information will be deleted permanently after this period.

Participants are also entitled to access data given under Freedom of Information legislation during storage. These measures ensure complete confidentiality, data protection, and compliance with GDPR requirements.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the research will be included in my MSc dissertation. The finalized dissertation will be placed in the college library and can be placed in an online repository if feasible. Publication or conference presentations are not presently scheduled, but results might be used to inform future academic debates or teaching materials. Participants' data will be anonymised in all the outputs. If further dissemination is required, participants will be advised suitably.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Researcher:
Rose Mariya Shaju
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Supervisor:
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