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ANALYSING EXPERT PERSPECTIVES ON THE INTEGRATION OF TARGETED DRUG DELIVERY (TDD) MECHANISMS WITH WIRELESS CAPSULE ENDOSCOPY (WCE): A QUANTITATIVE STUDY ON OPPORTUNITIES AND BARRIERS IN ADVANCING PRECISION GASTROINTESTINAL THERAPIES

BY

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A thesis submitted in partial fulfilment of the requirements for MSc. Medical Device Technology and Business

Innopharma Faculty of Pharmaceutical Sciences

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Candidate Declaration

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I hereby declare that this dissertation thesis "Analysing Expert Perspectives on the Integration of Targeted Drug Delivery (TDD) Mechanisms with Wireless Capsule Endoscopy (WCE): a Quantitative Study on Opportunities and Barriers in Advancing Precision Gastrointestinal Therapies" which is submitted for the master's degree of MSc in Medical Device Technology and Business, is prepared by myself and that the references is taken from the work of others, which has been cited and due acknowledgment has been given. I also here by declare that I have not plagiarised the work of anyone, either completely or partially, including any of the work of other students in this thesis.

Candidate signature:
Date: 24/08/2025

Supervisor name: Dr. Javed Iqbal

Supervisor Signature:
Date: 24/08/2025

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I thank God for I have the strength and the patience, and determination to compile this research at last. This journey would not have been possible without His guidance and blessings.

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I can never repay all that I owe to my dear mother. Her undying love support and belief in me is what has made me believe in myself the most. This victory is as much hers as it is mine.

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Abstract

Analysing Expert Perspectives on the Integration of Targeted Drug Delivery (TDD) Mechanisms with Wireless Capsule Endoscopy (WCE): a Quantitative Study on Opportunities and Barriers in Advancing Precision Gastrointestinal Therapies

Neehara Bijal Kumaraswamy

In this study we aim to examine experts' views on the opportunities and challenges posed by this integration and the role that it might be expected to play as part of a wider move towards personalised care. The research aims were to review state-of-the-art technologies pertaining to WCE and drug delivery, gather feedback via expert opinion from clinicians, engineers and pharmaceutical scientists and identify the technical, clinical and regulatory challenges as well as the future prospects for expanded use. A quantitative research design was utilised and an ANSI structured questionnaire was proposed to be administered to a purposive sample from clinicals, engineering and pharmaceuticals. The responses were analyzed using descriptive and inferential statistics. The results demonstrate that, although WCE has considerable potential as a non-invasive and patient-acceptable diagnostic and therapeutic modality, barriers to its widespread application exist. These are restrictions in capsule navigation, power consumption, biosensor integration, drug stability, dosage control, and regulatory approval mechanisms.

Still, some experts were hopeful about artificial intelligence, high-tech bio-sensors and multidisciplinary teams of researchers that could help clear these hurdles. It is argued, in this review, that effective incorporation of drug delivery strategies to WCE systems will depend on close convergence of technological innovation, clinical validation and regulatory acceptance. Strategic investment in R&D, clinician education, and global regulatory harmonization will be critical to move the needle on adoption. Finally, this study helps fill some of these gaps by providing a holistic, expert-driven assessment of WCE applications, and a roadmap for the potential role WCE play in the development of the next generation of precision GI therapies.

Keywords: *Wireless Capsule Endoscopy (WCE), targeted drug delivery, gastrointestinal therapies, expert perspectives, technological integration, regulatory barriers, precision medicine*

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List of Acronyms

AI – Artificial Intelligence

CE – Capsule Endoscopy

CMOS- complementary metal–oxide–semiconductor

CT – Computed Tomography

EMA – European Medicines Agency

FDA – Food and Drug Administration

GI – Gastrointestinal

MCCE- Magnetically controlled capsule endoscopy

ML – Machine Learning

MRI – Magnetic Resonance Imaging

N/A – Not Applicable

QMS – Quality Management System

R&D – Research and Development

TDDS - Targeted Drug Delivery System.

WCE – Wireless Capsule Endoscopy

MEMS - Micro-Electro-Mechanical-System

CDSCO- Central Drug Standard Control Organization

MCCE - Magnetically controlled capsule endoscopy

CRC - Colorectal cancer

NBI- narrow-band imaging

WPT - Wireless Power Transmission

Chapter 1: Introduction

1.1 Background of the study

The advent of wireless capsule endoscopy (WCE) has transformed what is referred to as gastrointestinal diagnostics. It has a low invasive modular and a sedation-free design that can be easily navigated by the user and acceptable by a patient (Cao *et al.*, 2024). This aids in the exploration of the GI track and the parts that could not be diagnosed using the conventional methods of endoscopy. Since the advent of the WCE methods, it has been capable of identifying and diagnosing gastrointestinal bleeding, small bowel tumours and Crohn disease. This has been mostly used because it is easy to engage hence a comfortable option due to the old modes (Ali *et al.*, 2025). Although it was designed as a gastrointestinal diagnostic device, a much more technologically advanced method was recently discovered on how to utilize it.

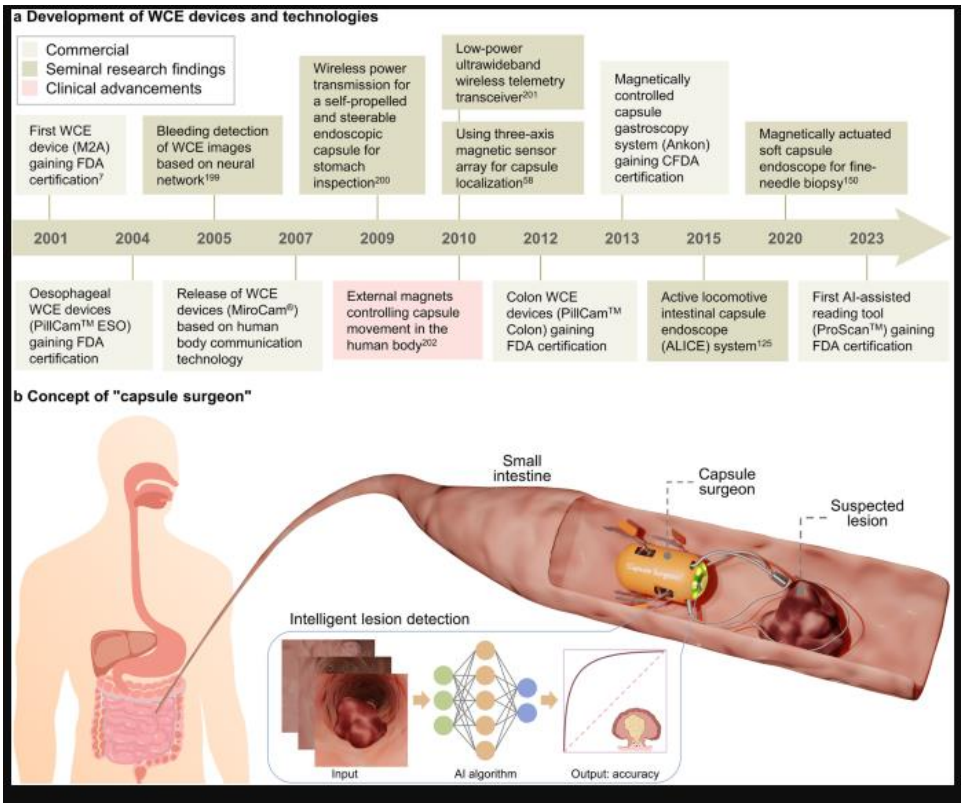

Figure 1: The image shows the functioning of a Wireless Capsule Endoscope (WCE) inside Gastrointestinal tract

(Source: Mehedi et al., 2023)

The WCE procedure could not only be applied to diagnose the gastrointestinal tract area but also locate and deliver the required medications in the system. Specifically, its drug delivery to the specific parts to extend the far and wide reach of the medication (Mehedi *et al.,* 2023). Using the technology to enable a drug infusion system in the capsule can provide medication delivery to the affected site. This, in turn, improves the drug administration and treatment process and has been proven to be effective for these scenarios. However, the drug administration process shows some difficulty, as there are many challenges to overcome in this matter. Firstly, the administrative drug must have a size that is easy to fit properly in the administration capsule of the WCE. In addition, clinical trials must require attention and approval of the government committee for the safe use of these products (Qin *et al*., 2022). Clinical clerks, doctors, and nurses must work in tandem to figure out the best possible care for the specific patients. Expert help and analysis are needed to understand the areas for development and the types of actions that can be taken to make the process easier and less time-consuming.

The gastroenterological diagnosis is expected to be revolutionised based on the presence of WCE, as it allows improved lesion detection rates (Ramoni *et al.,* 2025). It also aids in the process of addressing the exact nature of the lesion and curates therapeutic suggestions for better treatment. However, scanning accuracy could be further leveraged via the use of artificial intelligence (AI) assisted WCE technology. This way the targeted treatment for different diseases could be permitted without any delays, as WCE is faster and more convenient to boost the gastrointestinal therapies. The gastrointestinal therapies are getting upgraded with time, as the medical sciences are nowadays backed by strong technological influence and extensive clinical trials. The application of precision gastrointestinal (GI) therapies are essential in the modern era to accurately detect any form of irregularities with the gastric system in the human body. In many of the cases, lack of detailed endoscopy returns results which are complex to review for the doctors and gastro expert. A gastroenterologist gains an ample degree of assistance from an accurate diagnosis report, as targeted drug delivery mechanisms with WCE look to help achieve that and allow the experts in the medical field to cure many critical diseases associated in the gastro department. WCE might feature a lot of upgrades over the traditional endoscopy process. However, recent study has claimed that the use of WCE fails short against the more advanced Magnetically controlled capsule endoscopy (MCCE), which acts as a non-invasive, painless, comfortable, and safe equipment to

diagnose varied gastrointestinal diseases (Wang *et al.*, 2023). Therefore, the practical application of WCE needs to be reviewed in a detailed manner. Unless WCE becomes cost-effective for the patients, and fits the economies of scale, it cannot be treated as an inducer for better gastric health or a superior diagnostic tool.

1.2 Problem statement

Transforming the Wireless Capsule Endoscopy (WCE) device to a dedicated drug administration device needs a proper understanding of the product and its use. Changing the tool's original purpose to serve as a technologically advanced therapeutic tool has a lot of problems to overcome. These challenges include technical, clinical and regulatory standards and practices. However, apart from its original promise, there are ways to make this product a multi-purpose tool for both diagnosis and administration (Muruganantham and Balakrishnan, 2021). The primary problem is the miniaturisation of the drug admixture capsule to fit in the WCE, without damaging or decomposing it. This, however, must not compromise the quality or the intended purpose of the WCE (Wang *et al.*, 2025). The process shifts towards miniaturising the drug ampule with advanced are and proper technological assistance. This also needs the machine to have a controlled release and retract system, along with its precise locating technologies for pepper drug administration.

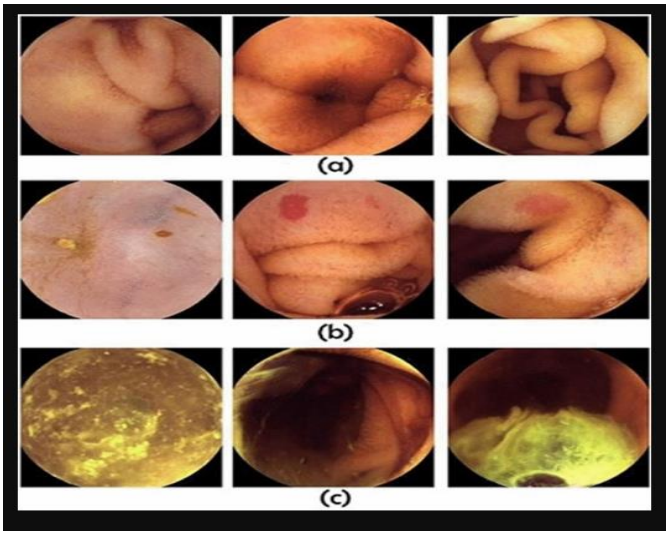

Figure 2: Image showing the pictures of different parts of intestine taken by the Wireless Capsule Endoscope

(Source: Jain *et al.*, 2021)

This research has obtained practical and theoretical data of significance and detail. In the practical use of the WCE integration of targeted drug administration systems, bringing forward a multi-channel approach can be beneficial for future development. However, it may not be simple to adopt a device that needs expert supervision and proper care, with its technologically advanced use case scenario (Bajhaiya and Unni, 2024). Positioning techniques for the module have to be done accurately, as it is needed for the administration of the drugs in the proper place and alignment. For this scenario, the creation of an advanced navigation system is also required, as there cannot be a proper drug administration without locating the problem zone (Ionescu *et al.*, 2022).

Taking a more regulatory approach, it can be said that the WCE must be classified as a multi-function tool for future reference, and its use may be diversified for a better approach. However, the tools must undergo a thorough regulatory check under the pharmaceutical guides and medical devices (Jain *et al*., 2021). The properties of a multi-tool with dual functions create a longer developmental timeline, making the process a time-consuming one. In addition, the wireless transfer of data files creates a risk of severe cybersecurity concerns and breaches of data privacy.

Clinical background of the problem faced by the researcher in creating a device that can have dual properties of use and accessibility can be found to be developmental for the medical science community. However, as some prototype devices have shown, development and user accessibility need to be further developed for their use (Hany, Hye and Akter, 2023). There are many factors that need to be executed carefully if the device is to function properly. The diversification of the problems created in this research paper has also been subsided for the development of the WCE (Naser, Naser and Shehata, 2022). It can be seen that there are many problems regarding the development of the WCE device, and most of them are followed by regulatory constraints and their intended application procedures for the patient.

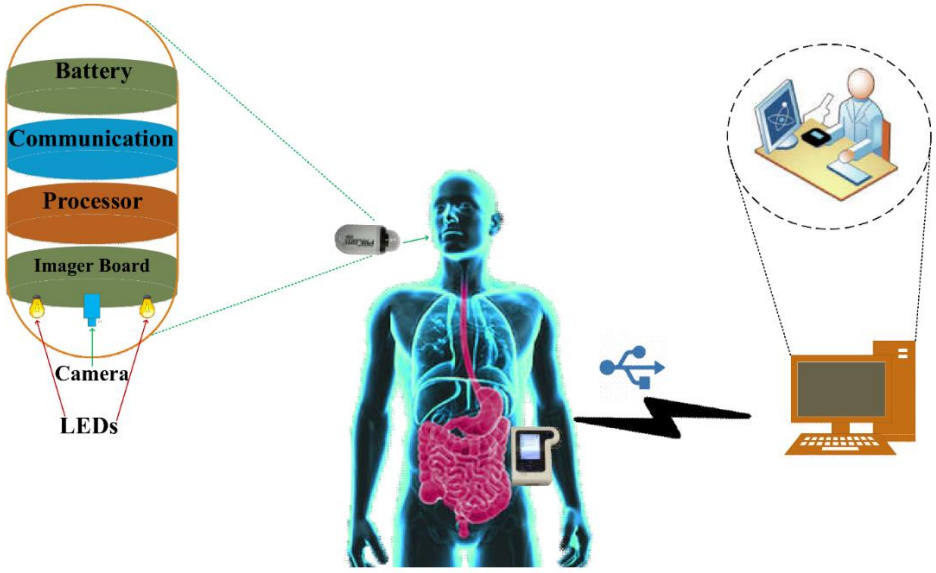

Figure 3: The image showing the working of a Wireless Capsule Endoscope (WCE)

(Source: Xiao *et al.*, 2023)

In addition, the study presents the absence of a consolidated evaluation of the product and its use through its public shareholders and stakeholders (Shah *et al.* 2023). Then, the evaluation of the opportunities and regulatory standards must be observed for the timely and effective application of this system. This research and technological gap hinder the use and adaptation of promising innovations and technological advancements in routine checks of everyday life (Xiao *et al.*, 2023). Without the help and presence of prior insights, these data cannot be used in creating better prospects for the use of this device (Cao *et al*., 2024). Protocols that are imminent in the development of this system and its use have similar literature and data gaps that have been holding back the progress needed to develop this system.

WCE features minimal invasive imaging, as it can be combined with site-specific drug release systems to ensure that diagnosis of a patient is done with high level of accuracy. This shall help in the process of discovering Crohn's disease, ulcers, and colorectal cancer possibilities faster, and thereafter generate a protocol to deal with these diseases. The combination of WCE with the targeted therapy is observed to be a hybrid process where cost effectiveness would be a concerning factor. On the other hand, there are associated factors, such as feasibility, safety, and clinical adoption that would play a vital role in signifying the merit of this hybrid technology in the long run in the medical field. The use of WCE is quite common in pediatric small bowel investigation,

as it has been done for over 20 years (Thomson, 2021). However, the capabilities of this method to merge with the targeted therapy is area left unexplored. Hence, it is vital to figure out the therapeutical benefits obtainable from the combination of WCE and targeted drug application in patients suffering from any kind of gastric disease.

The barriers are far more concerning for the application of WCE and targeted therapy as a combination because there will be regulatory and ethical pressure. The worldwide acceptance for such as niche and sophisticated medical solution could be less, citing lack of practical success or real-world application. The access to advanced medical devices also draws a lot of complexities surrounding the worldwide reach of the diagnosis. Therefore, further set of clinical trials are needed in order to create a bigger acceptance rate for the hybrid medical technology. While it is believed that the regulatory pressure would decline in the future as the clinical evidence would be there to back the hybrid use of WCE and targeted therapy in the diagnosis of gastrointestinal diseases. Colorectal cancer (CRC) acts as a significant global health burden, but the use of targeted therapy is expected to reduce the crisis generated from CRC among different group of patients (Al-Jaber, Biswas and Al-Mansoori, 2025). Since targeted therapies are preferred by many of the gastroenterologists and oncologists to treat cancer cells, the use of WCE in combination with targeted therapy could help assess the root cause for these diseases and follow better intervention protocol.

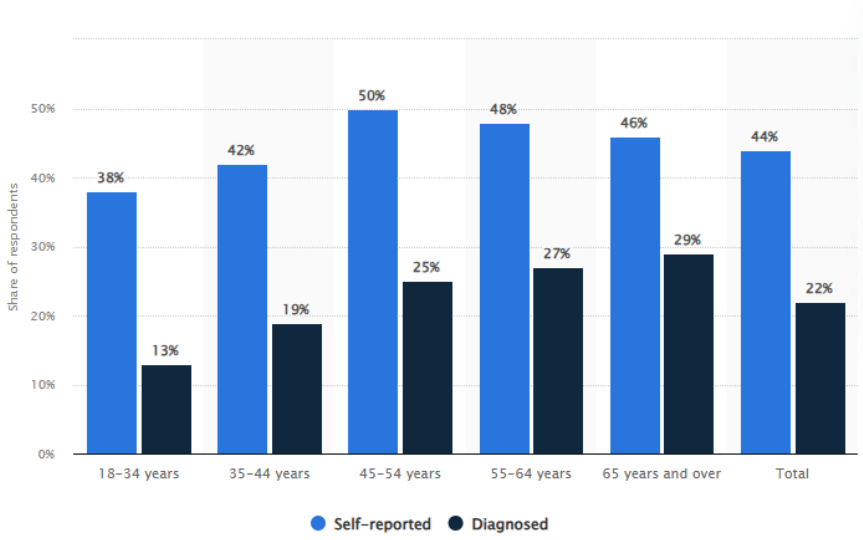

Figure 4: Share of adults diagnosed with gastrointestinal conditions in UK

(Source: Gagliardi, 2024)

The need for precision GI therapies is immense in the modern world. As per statistical reports, UK witnessed high percentage of population aged 65 and above to have gastrointestinal condition. Historical figures indicated 29% of the people aged 65 years and over had a gastrointestinal condition as per diagnosis, with the population average remaining at 22% out of the 44% self-reported cases of gastrointestinal problems (Gagliardi, 2024). This goes to suggest that to diagnose and treat the gastrointestinal diseases, the medical institutions need a better tool. It is assumed that WCE and targeted therapy in a combined manner shall pave the way for faster and efficient diagnosis of the patient condition, who registered to possibly share a gastrointestinal problem. There are departments who would benefit widely from the application of the hybrid medical solution, such as gastroenterology, biomedical engineering, and nanotechnology. Refining the treatment will become easier for the medical experts once they can review the diagnosis reports in a comprehensive manner during the process of WCE and targeted therapy. The software advancement in imaging is made possible as a result of AI adoption in the field of healthcare, which has also contributed towards better WCE (Hanscom and Cave, 2022). This goes to indicate that WCE disadvantage of obtaining targeted diagnoses could be made better with advancements in technology.

There are key constructs or variables associated with the research that help recognise the importance for evaluating the hybrid medical technology in the form of WCE and targeted therapy and discover whether it carries more benefits as compared to constraints in dealing with the better application of GI therapies. The technological feasibility, clinical applicability, economic factors, regulatory measures, and adoption barriers act as the independent variables in the research. The application of WCE and targeted therapy in a combined manner and the perceived value derived from it has become the dependent variable. Since the study has adopted the quantitative route to compare the feasibility of this hybrid technology for better GI therapies, it manages to highlight the key drivers or the success factors for WCE and targeted therapy in improving GI therapy outcomes. Furthermore, the quantitative study has also addressed the ways based on which the barriers to the application of WCE and targeted therapy could be reduced.

This research has shown the gaps in the news of the stakeholders and their use of technological matters that are related to the delivery of medicine through the use of the WCE system. Through the systematic capturing and analysis of expert knowledge and found data, this study can bridge

the gaps between the information and its intended application in the hands of healthcare professionals and biomedical engineers.

1.3 Research Aim

- Exploration of expertise and technological advancements in the integration of targeted drug delivery mechanisms in Wireless Capsule endoscopy (WCE) in the identification of challenges, opportunities and usability in creating advanced options in gastrointestinal care.

1.4 Research Objectives

i. To review advanced technological systems in the delivery of Wireless Capsule Endoscopy (WCE) and targeted drug delivery systems for gastrointestinal problems.
ii. To gather data and expert opinions from clinical doctors, biomedical engineers, and pharmaceutical researchers for the use of WCE as a device for internal drug administration.
iii. To identify technical, Clinical and regulatory barriers for the integration and use of these systems.
iv. To assess future benefits and opportunities to integrate into the systems and explore further opportunities for a greater and advanced implementation of the system.
v. To use recent advancements in technical and biomedical departments to develop a certain patient-specific approach for the delivery of better care in related matters of WCE applications.

1.5 Research Questions

i. What are the recent advancements that have been made in the field of biomedical science and Wireless Capsule Endoscopy (WCE)?
ii. How do the doctors, clinicals, bio-medical engineers and pharmaceutical engineers perceive the usability and developmental aspects of the WCE?
iii. What are the problems regarding the technical, clinical and regulatory barriers and problems for the WCE methods in both drug administration and internal diagnosis?

iv. What are the potential benefits and opportunities that can be found essential and useful in future for the adoption of the WCE?

1.6 Significance of the study

This study has been developed through acquiring and adapting data from various research articles. Thorough, practical and theoretical approach. Practical evolution of drug theory and application methods is to be followed in this research. Methods will be introduced that improve the patient outcome and reduce side effects. Findings will help in the research design and their use in applications for future development. The research sheds light on the limited operator and user knowledge of the WCE systems. This will also address approval challenges and regulatory aspects of the device and its use in different scenarios. However, there are matters of importance that have been used to develop this study.

1.7 structure of the dissertation

The dissertation is divided into five chapters. The first chapter explores the introduction of the research problem and its use in creating a better research direction with aims and questions. Then, chapter 2 delves into the comprehensive literature review that helps create the research problems, solutions, and technology adaptation. In Chapter 3, the methodology of the research and its use are explained in creating a better research study and for future reference. This also presents the research in a philosophical approach and the methods that have been used to analyse the data. Chapter 4 represents the findings in the research and their use. Then, lastly, chapter five provides the discussion and conclusion.

Chapter 2: Literature Review

2.1 Introduction

The fusion of Targeted Drug Delivery (TDD) and Wireless Capsule Endoscopy (WCE) represents a groundbreaking shift in precision Gastrointestinal (GI) therapy, offering a new approach to the combined diagnosis and treatment of diseases in a less invasive fashion. (Su, 2025; Leenhardt et al., 2021). WCE is an orally ingested camera device, which has revolutionized GI diagnostics by providing a direct view of the mucosa that is otherwise impossible to reach, while TDD enables targeted drug release, limiting the systemic adverse effects and enhancing therapeutic efficacy. (Tekade et al., 2017). Combining such technologies would address the limitations of present GI interventions such as delay in diagnosis-to-treatment times and lack of drug target specificity. Yet seamless integration is predicated on addressing clinical, technical and regulatory challenges particularly in heterogenous healthcare markets like that in India and Ireland. This review of literature consolidates available evidence, examines technological models, and discusses expert opinions for understanding potential advantages, limitations, and future directions to develop integrated WCE-TDD systems for enhancing high-quality GI health care.

2.2 Overview of Wireless Capsule Endoscopy (WCE)

2.2.1 Evolution of Capsule Endoscopy Technology

The concept of capsule endoscopy (CE) is emerged in the early 1980s when Israeli engineer Gavriel Iddan, who is inspired by discussions with gastroenterologist Eitan Scapa, identified the limitations of fiber-optic endoscopy in imagining the small bowel (Iddan et al., 2000). Technological developments, especially the introduction of complementary metal–oxide–semiconductor (CMOS) imaging sensors, facilitated low-power, miniaturized cameras appropriate for ingestion (Fossum, 1997). By 1993, Iddan developed a three-part system that contains an external recorder with abdominal sensors, a swallowable camera capsule with a transmitter, and image-processing software. Collaborations with engineers like Dov Avni, and the founding of Given Imaging in 1998, were crucial in refining the CMOS imager, combining light-emitting diode (LED) illumination, and improving optical design (Swain et al., 2001). Analogous research by Paul Swain in the UK proved wireless transmission from miniature cameras. Swain became the

first human to experience CE in 1999. After that, FDA clearance and CE Mark approval are obtained in 2001, marking clinical debut of CE. Since then, CE has transformed small bowel imaging, allowing non-invasive, patient-friendly diagnostics and encouraging rapid technological and clinical adoption globally (Iddan et al., 2000; Rey et al., 2004; Adler et al., 2017).

2.2.2 Current Applications in Gastrointestinal Diagnostics

Wireless Capsule Endoscopy (WCE) has developed as a transformative technology for non-invasive visualization of the GI tract, allowing diagnosis of a wide range of conditions that are often unreachable with traditional endoscopy. Medtronic's PillCam series is extensively utilized in clinical practice. The PillCam SB 3 offers complete visualization of the small bowel for identifying iron deficiency anaemia, Gastro Intestinal (GI) bleeding, and Crohn's disease, with high-resolution imaging and adaptive frame rates (Eliakim et al., 2010; Franco et al., 2017). The PillCam Crohn's capsule provides targeted imaging for Crohn's disease without sedation or radiation, whereas the PillCam COLON 2 helps in colorectal polyp detection with dual-camera, wide-angle imaging (Baltes et al., 2018; Deding et al., 2020).

Other prominent devices comprise IntroMedic's Miro capsule, intended to examine the small intestine with prolonged battery life (Kim et al., 2007), and Jinshan's OMOM capsule (name of a Wireless Capsule Endoscope), which assesses the duodenum, stomach, colon, and small intestine with innovative MEMS imaging (Friedrich et al., 2013). The Capsocam Plus offers a 360° view for small bowel assessment, predominantly in bleeding and Crohn's disease patients (Zwinger et al., 2019), whereas Ankon's Navicam enables targeted gastric mucosa visualization with magnetic guidance (Liao et al., 2016).

Clinically, WCE is implemented for detecting Angio ectasia, ulcers, strictures, and tumors, and also for polyp recognition and GI bleeding assessment. Artificial Intelligence (AI)-assisted image analysis further improves diagnostic accuracy, attaining sensitivities and specificities surpassing 95% in many studies. The incorporation of WCE into routine practice lessens the requirement for invasive procedures, enhances patient comfort, and enables earlier diagnosis of GI disorders, contributing significantly to precision gastroenterology in India and Ireland.

2.2.3 Limitations of Conventional WCE

While Wireless Capsule Endoscopy (WCE) offers a painless, minimally invasive option compared to traditional wired endoscopy, it has significant limitations. One major drawback is that it cannot

perform biopsies or treatments, so its use is limited to diagnostic imaging alone (Pennazio et al., 2006). In contrast, regular endoscopy allows for tissue sampling and immediate treatment of detected lesions. Moreover, WCE lacks newer imaging techniques like narrow-band imaging (NBI), which improves mucosal visualization and helps in early abnormality detection during conventional endoscopy.

Accurate location of the capsule in the GI tract is still a challenge due to complex anatomy and peristaltic movement, particularly in the small intestine. Although methods like inertial measurement units, magnetic guidance, and Artificial Intelligence (AI)-driven image analysis have been investigated, achieving consistently accurate positioning remains difficult (Wang et al., 2013). The technology also faces limitations because of its short battery life, usually lasting between 8 to 12 hours, which can restrict complete visualization during slow intestinal transit.

Variation in resolution among capsule models (ranging from 256 × 256 to 640 × 480) can affect diagnostic accuracy, particularly for subtle lesions. Additionally, the lengthy review time up to 2 hours to analyze around 50,000 images places a significant burden on clinicians (Rahim et al., 2020). Lastly, the passive, self-propelled movement of WCE does not allow for control over the capsule's orientation or speed, potentially resulting in incomplete or suboptimal imaging of certain areas. These drawbacks emphasize the need for ongoing technological advancement, especially in adding treatment options and improving both localization accuracy and imaging quality.

2.3 Targeted Drug Delivery in Gastrointestinal Therapies

Targeted Drug Delivery System (TDDS) have transformed the treatment of Gastro Intestinal (GI) disorders by enhancing drug bioavailability, lessening systemic side effects, and refining therapeutic efficacy. These systems utilize the unique physiological and biochemical properties of diverse GI segments to attain site-specific drug release.

2.3.1 Principles and Mechanisms of Targeted Drug Delivery

Targeted drug delivery in the Gastro Intestinal (GI) tract relies on interactions that are specific to the site. These are influenced by factors such as enzyme activity, pH levels, mucus composition, and epithelial cell receptors (Zhang et al., 2020). One important strategy is muco-adhesion, where polymers like chitosan and poly (acrylic acid) stick to mucosal surfaces. This helps hold onto the drug longer and improves local treatment effects. Another important method is receptor-mediated

endocytosis, where ligands such as folic acid or bile acids target receptors that are in excess on enterocytes or M cells. This boosts systemic absorption and cellular uptake (Banerjee et al., 2016). Additionally, pH-responsive drug release systems, like coatings such as Eudragit, allow for site-specific delivery by dissolving at set pH levels. This enables precise drug release in the colon or intestine. CD Bioparticles develops nano-carriers, including liposomes and polymeric nanoparticles, that are modified with targeting ligands to enhance treatment effectiveness and drug availability. By using these methods, Targeted Drug Delivery System (TDDS)s improve treatment precision, lessen systemic side effects, and provide major benefits for therapies aimed at GI disorders.

2.3.2 Current Drug Delivery Systems for GI Disorders

Current drug delivery systems for gastrointestinal (GI) diseases include several innovative approaches, each designed to improve how well medicines reach their target. Gastroretentive systems, such as floating tablets and mucoadhesive patches, help extend the time a drug stays in the stomach, which can enhance absorption (Wang et al., 2020). For conditions affecting the colon, polysaccharide-based nanoparticles are often used. These carriers take advantage of the colonic microbiota to trigger local drug release, making them especially useful for treating inflammatory bowel disease and colon cancer (Laroui et al., 2011). Another strategy involves mucus-penetrating particles such as Polyethyleneglycol (PEG)ylated nanoparticles which are designed to avoid being trapped in the thick mucosal layer. This allows them to reach the underlying epithelium more effectively, improving both absorption and systemic availability (Crater & Carrier, 2010). Not-withstanding these advancements, issues such as pH variations, enzymatic degradation, and unequal absorption across different GI segments remain significant challenges. The need for more precise delivery techniques is highlighted by these disadvantages, which promotes the adoption of cutting-edge technologies like Wireless Capsule Endoscope (WCE). Site-specific drug release and real-time monitoring are made possible by WCE, which combines targeted delivery and diagnostics to enable personalized therapy. With these advancements, GI drug delivery may advance to the next level, improving therapeutic efficacy and reducing systemic side effects (Subramanian et al., 2022).

2.3.3 Limitations and Need for Integration with WCE

In spite of their potential, current Targeted Drug Delivery System (TDDS) for Gastro Intestinal (GI) therapies face several limitations. Variable GI transit times can interrupt drug release consistency, resulting in unpredictable therapeutic outcomes (Kagan & Hoffman, 2008). Moreover, the dense mucus barrier affects nanoparticle penetration, while minimizing drug absorption at target sites (Boegh & Nielsen, 2015). Also, passive accumulation of drugs often leads to low targeting precision, lessening therapeutic efficiency (Yu et al., 2016). Hence, integrating TDDS with Wireless Capsule Endoscopy (WCE) provides promising solutions. WCE facilitates real-time imaging, allowing precise drug release at diseased locations (Munoz et al., 2019), whereas feedback-controlled delivery systems utilize pH or biomarker sensors to improve drug dosing (Steiger et al., 2021). CD Bioparticles supports this progression by creating WCE-compatible nano-carriers that combine diagnostics and therapy, paving the way for personalized GI treatments. By addressing current limitations, this integrated method improves drug delivery accuracy and efficacy, with better patient outcomes.

2.4 Technical Advancements in WCE Systems

Wireless Capsule Endoscopy (WCE) has evolved significantly in terms of six core aspects active locomotion, endurance, communication, localization, visual lesion detection, and diagnostic/therapeutic functions. Conventional technologies confront several limitations, prompting the growth of intelligent alternatives to fulfil the vision of a "capsule surgeon." Endurance improvements are based on power supply innovations. Traditional silver oxide batteries last 8 to 10 hours but restrict advanced functionalities. Lithium-ion polymers provide higher power density but increase safety concerns. Self-powered batteries harness gastric fluids but confront low output challenges (Chen et al., 2022). Edible electronics, such as batteries, supercapacitors, and nanogenerators, offer safety benefits but struggle with limited energy density. Wireless Power Transmission (WPT) shows potential for continuous, high-efficiency energy transfer without onboard batteries, releasing internal space for other modules (Sharova et al., 2021).

Active locomotion solves the limitation of passive movement through gastrointestinal peristalsis, which leads to high lesion omission rates and retention risks. Magnetic control, allowing contactless and precise navigation using external magnets, has revealed high visibility rates and clinical feasibility, making it a foremost solution for controlled navigation (Kim et al., 2022).

Communication in WCE traditionally depends on radio frequency, but bandwidth constraints affect high-quality video transmission. Ultra-wideband offers higher data rates and lower power consumption, even though regulations and hardware costs are barriers (Li et al., 2021).

Localization ensures precise capsule tracking for diagnosis and control. Radio Frequency (RF) localization provides cost-effective integration but restricted directionality. Magnetic localization struggles with tissue interference and attains millimeter-level accuracy, though challenges exist in rotation angle detection. Video-based localization, supported by AI, utilizes image analysis for positioning without extra hardware but suffers from latency problem. Hybrid systems that combine video with RF or magnetic methods enhance precision (Zeising et al., 2022). Visual lesion detection benefits from Artificial Intelligence (AI) advancements that automate analysis of the 60,000+ images produced per examination, attaining more than 95% diagnostic accuracy in detecting tumors, bleeding, polyps, and ulcers. AI decreases physician workload, rises consistency, and supports rapid diagnosis (Rahim et al., 2020). Diagnostic and therapeutic functions have extended with integrated sensors for temperature, pressure, pH, biochemical detection, and imaging beyond the visible spectrum. Miniaturized mechanical tools enable biopsies, bleeding control, and Targeted Drug Delivery System (TDDS). Magnetic control further allows accurate, minimally invasive therapeutic interventions (Qiu et al., 2019). These progressions are shifting WCE from a passive imaging device into an intelligent, controllable, and multifunctional medical platform.

WCE is progressive through key technologies, which are discussed as follows. Near-field wireless power transmission improved through optimized coil design for optimal efficiency and stability. Magnetic field active drive improved safety and control over sophisticated coil configurations. Intrabody communication benefited from bidirectional links and conformal antennas. Hybrid localization merged RF, magnetic, and vision data for millimeter accuracy (Sharova et al., 2021). By using transfer learning, AI-driven lesion detection improved diagnostic precision. Magnetic-controlled diagnosis and treatment empowered liquid sampling, targeted biopsy, and drug delivery through magnetic actuation and soft robotics, collectively improving safety, efficiency, and therapeutic capabilities of WCE.

2.5 Integration of Targeted Drug Delivery with WCE

Wireless Capsule Endoscopy (WCE) has emerged as a revolutionary diagnostic tool for Gastro Intestinal (GI) pathologies, including Crohn's disease, obscure GI bleeding, and small intestinal tumours. Traditional WCE systems, like the M2A capsule and Olympus's EndoCapsule, use complementary metal–oxide–semiconductor (CMOS) sensors to capture images of the intestinal lumen but did not have therapeutic capabilities (Iddan et al., 2000; Olympus, 2005). In spite of their diagnostic utility, these systems cannot provide targeted therapies for conditions such as ulcerative colitis, highlighting a critical clinical requirement (Eliakim et al., 2006). Hence, researchers have developed drug-delivering WCE platforms, like Innovative Devices' InteliSite, Philips' IntelliCap, and Phaeton Research's Enterion capsule, to release medication in particular GI regions (Swan et al., 2009). However, these systems failed in precision because of peristaltic movement and inability to anchor at target sites (Woods et al., 2012).

A novel micro-robotic WCE platform combines a holding mechanism to fight peristaltic forces and a needle-based targeting system for localized drug delivery (Miftahof, 2005). The device is designed within a 3 cm^3 volume for swallowability (Connor et al., 2009). It uses a 360° needle-positioning mechanism through a micro-motor, facilitating precise penetration of the intestinal wall (Woods et al., 2012). The operation of the system includes remote-controlled anchoring, real-time imaging, and needle deployment for delivering 1 mL of medication through a shape-memory alloy actuator (Carpi et al., 2006). Challenges are localizing the capsule and optimizing power consumption for multi-dose delivery (Wang et al., 2006). This integration of diagnostics and therapy represents a transformation toward personalized GI treatments.

Integration of Targeted Drug Delivery (TDD) systems with WCE shows a significant leap in convergence of therapeutics and diagnostics for gastrointestinal care. Unlike the interventions of conventional endoscopic, which separate diagnosis from treatment, the combined platform helps the clinicians deliver localised therapy and visualise diseased tissue in real time, reducing treatment cycles and minimising systemic exposure. A lens, Light Emitting Diode (LED), image sensor, antennas and button battery are included in standard WCE devices, which are normally 11 × 26 mm in size (Cao et al., 2024). Recent research emphasises the incorporation of micro-reservoirs, sensor-based and nano-carrier release mechanisms for capsule designs, through enabling precision-controlled release triggered through biomarker, pH or enzyme signals. This

assures drug deployment happens at the optimal site, enhancing therapeutic efficacy of conditions like Crohn's disease, localised infections and colorectal cancer.

Additionally, advances in magnetic navigation and active locomotion addressed challenges for positional accuracy, thereby improving site-specific for targeting. Despite these advances, this technology is facing hurdles in biocompatibility, energy limitations and miniaturisation of integrated drug reservoirs. Interdisciplinary collaboration among gastroenterologists, biomedical engineers and pharmaceutical scientists is important for refining prototype systems to clinically viable solutions. Autonomous WCE system must be able to track capsule's trajectory in real time and have a control system that can continue navigating based on data collected in order to ensure safe navigation (Ali et al., 2025). Furthermore, it is preferable to have access to the capsule's trajectory data to create precise user profiles for future reference and diagnosis. Ultimately, integrated WCE-TDD platforms personify promise for personalised precision therapy, streamlining care for patients through merging treatment, diagnosis and monitoring to a single minimally invasive process.

2.6 Current Landscape in India and Ireland

2.6.1 Technological Development and Clinical Adoption in India

India has made substantial strides in adopting Wireless Capsule Endoscopy (WCE) for diagnostics, with increasing research into Targeted Drug Delivery System (TDDS) applications. The Indian Council of Medical Research (ICMR) has supported the researches on nanoparticle-based drug carriers for GI diseases, mainly for inflammatory bowel disease and colon cancer (Elumalai et al., 2024). However, clinical adoption is limited because of high costs and infrastructure constraints in rural healthcare environments (Patel & Desai, 2023). Indian startups, like Aubot Medical and Perfint Healthcare, are developing low-cost WCE systems along with AI-assisted diagnostics (Tiwari et al., 2012). All India Institute of Medical Sciences (AIIMS) are investigating mucoadhesive nanoparticles and pH-responsive drug release mechanisms for localized therapy (Ismail & Kishore, 2025). In spite of these progressions, regulatory challenges and a lack of large-scale clinical trials affect widespread implementation. Recently, India also focused on the indigenous innovations for reduce dependency of lower overall costs and imported capsule systems. Institutions like "National Institute of Pharmaceutical Education and Research" (NIPER)

and "Indian Institute of Technology" (IIT) are collaborating on the hybrid prototypes, which integrate AI-based lesion detection with localised modules for drug dispensing. Pilot trials of the tertiary hospitals illustrate feasibility of mucoadhesive nanoparticles administered through capsule endoscopy for ulcerative colitis management, while large-scale validation is pending. Furthermore, government initiatives such as "Make in India" and funding from the "Department of Biotechnology" (DBT) are speeding up translational research. For more than 10 years, researchers have been looking into potential AI techniques to enhance the diagnosis and evaluation of ulcers and mucosal inflammation brought on by Crohn's disease (George et al., 2024). These efforts emphasise the dual approach of India's innovation and affordability, aiming to make recission gastrointestinal therapies accessible for diverse healthcare settings.

2.6.2 Research Innovations and Healthcare Integration in Ireland

Ireland has developed as a leader in Wireless Capsule Endoscopy (WCE)-integrated drug delivery, which is driven by strong academic-industry collaborations. The Tyndall National Institute and University College Dublin (UCD) are pioneering smart capsules along with controlled drug release and real-time imaging (Lamprou et al., 2023). PillCam with drug-eluting capabilities is the key innovation, which is developed in partnership with Medtronic, which is experiencing clinical trials for Crohn's disease treatment (Cortegoso Valdivia et al., 2021). Irish Health Service Executive (HSE) has combined WCE diagnostics into public healthcare, with strategies to expand into therapeutic applications (Ross et al., 2020; Kotla et al., 2019). Furthermore, Irish startups such as Capsos Medical are investigating magnetically guided capsules for site-specific drug deployment. India is advancing in low-cost WCE diagnostics, whereas Ireland is progressing in therapeutic WCE innovations.

In Ireland, integration of WCE with targeted drug delivery for strengthened through strong academic and industry partnerships, mainly with Medtronic and leading universities. Research groups at the Tyndall National Institute and Trinity College Dublin are pioneering sensor-enabled capsules capable for biomarker responsive drug release and pH triggered, enhancing precision treatment of the colorectal cancer and inflammatory bowel disease. Clinical pilots of the "Health Service Executive" (HSE) network explored patient results through the use of smart capsules with a real-time mechanism for feedback, reduced need for an invasive process and demonstrated higher

treatment adherence. However, Ireland's alignment with the "EU Medical Device Regulations" fosters faster cross-border collaborations and clinical translation. In addition to being utilised in clinical settings, capsule endoscopy has been combined with artificial intelligence and deep learning for use in diagnostic and therapeutic research (Liu et al., 2023). This ecosystem aims to position Ireland as a frontrunner for therapeutic WCE innovations under a strong worldwide commercialisation potential.

2.7 Regulatory and Ethical Considerations

India regulates medical devices, including Wireless Capsule Endoscopy WCE and Targeted Drug Delivery System (TDDS), under the Drugs and Cosmetics Act and Medical Devices Rules. The Central Drugs Standard Control Organization (CDSCO) categorises WCE as a Class C device (moderate-high risk), necessitating clinical trials for approval (CDSCO, 2021). Ethical clearance from the Indian Council of Medical Research (ICMR) is compulsory for human trials, highlighting informed consent and data privacy (ICMR, 2017). However, delays in approvals and fragmented state-level regulations are difficult. Ireland follows the EU Medical Device Regulation along with the Health Products Regulatory Authority (HPRA) managing compliance (HPRA, 2020). Ethical reviews are performed by Research Ethics Committees (RECs), which is in line with GDPR for data protection. Irish streamlined process quickens innovation, as observed in the PillCam™ SB3's adoption (Medtronic, 2021). Divergent standards between India and the European Union (EU) obscure collaborations. Although India's New Drugs and Clinical Trials Rules in 2019 intend to align with global norms, variations in risk classification and trial protocols continue (IMDRF, 2023).

TDD integration with WCE raises complex ethical and regulatory considerations which vary among jurisdictions however, it remains central for ensure the safety of patients, public trust and device reliability. The medical devices of India are regulated through the "Central Drugs Standard Control Organisation (CDSCO) under Medical Device Rules 2017" and the "New Drugs and Clinical Trials Rules 2019" (Trivedi et al., 2025). As system confidence increased, businesses flooded the market, resulting in additional worldwide trials. In 2006, the CDSCO introduced fast-tracking for clinical research to reduce the application evaluation period from sixteen weeks to ten weeks. The DCG (I) created two application categories: Category (A) comprises those that are also

being conducted in countries with well-established, functional regulatory systems, and Category (B) comprises all other situations.

Under the dynamic of "New Drugs and Clinical Trials Rules 2019", that cover different categories, like new medications, "bioavailability/bioequivalence" (BA/BE) studies and "investigational new drugs" (INDs), fee are simplified. These redesigned fees are transparent and consistent than the previous structure, that frequently lacked consistency and transparency (Trivedi et al., 2025). This change purpose to ensure reasonable fees, encourage compliance and reduce ambiguity with legal requirements. The revised approach are considers evolving regulatory landscape, underscoring efficacy and promoting innovation in the dynamic of clinical research. These rules increase openness, reduce approval waits and speed up processes for bringing India closer to the several international standards. Comparing it crucial elements including application and approval processes, regulatory decision timelines, trial monitoring methods, ethics committee requirements and informed consent rules. Additionally, India also shortened their date for approval, Europe enforce standardised norms under the framework of "Clinical Trials Regulation" (CTR) and the USA places a priority on completing the preclinical requirements of data.

However, Ireland generally operates under the "European Union's Medical Device Regulation" (EU MDR 2017/745) framework, which provides a streamlined process for product combinations while ensuring stringent quality and safety standards. Oversight by the mandatory ethical approval in "Research Ethics Committees" (RECs) and "Health Products Regulatory Authority" (HPRA) fosters compliance with the "General Data Protection Regulation" (GDPR) and "Good Clinical Practice" (GCP). In this regard, it is necessary to ensure the availability and safety of various systems that are intended to enhance or save lives. Due to the size and diversity of this sector, certain regulations are required. The new Regulation MDR (EU) 2017/745 just went into effect, bringing with it more and more specific criteria on the actions of the parties engaged in the medical device development procedure (Bianchini and Mayer, 2022). Regulations, as opposed to previous Directives, are immediately enforceable under national law, which lessens disparities within the EU.

Overall, the Directives' requirements have not been altered, and MDR has introduced new ones. It is important to note that the new procedure, which introduces a data-supported life-cycle approach to safety, requires that all medical devices be recertified.

2.8 Challenges in Integrating Targeted Drug Delivery with WCE

Integrating Targeted Drug Delivery System (TDDS) with Wireless Capsule Endoscopy (WCE) presents several challenges. Precise localization within the dynamic GI environment is crucial, as imprecise positioning can lessen treatment efficacy or risk healthy tissue exposure. Attaining controlled, on-demand drug release necessitates reliable actuation mechanisms, often reliant on magnetic fields or microvalves, which should be reduced without compromising capsule power or functionality. Limited onboard energy limits prolonged operation, making effective power management vital. Biocompatibility of drug reservoirs and delivery mechanisms is crucial for preventing adverse tissue reactions. In addition, variations in motility, GI anatomy, and pH complicate consistent delivery performance across diverse patients. Real-time monitoring of capsule location and drug release is complex because of signal attenuation within the body. Manufacturing cost, complexity, and ensuring safety during active control further affect clinical translation. Addressing these challenges demands developments in localization accuracy, actuation reliability, energy efficiency, and integration of sensing with therapeutic systems.

Integrating Targeted Drug Delivery (TDD) with Wireless Capsule Endoscopy (WCE) offers a multifaceted set of challenges, like spanning technical, patient-centred, clinical and regulatory dimensions. From a technical point of view, the most crucial limitations lie in power management and miniaturisation. Incorporating the reservoirs of drug imaging, actuators, and sensor systems of a swallowable capsule increases design complexity, while finite battery life stops multi-dose functionality and long-term operation. Drugs are shielded from the severe conditions of the gastrointestinal tract by their encapsulation. This would minimise the loss of the active ingredients while lowering the biological barriers that present different difficulties. The capacity of these nanocarriers to create combination therapies, in which many medications are administered simultaneously, is another benefit. These methods of simultaneous delivery allow the medications to work in concert (Zheng et al., 2025). Their ability to be altered to allow for the controlled release of medications in particular bodily areas is another advantageous feature.

Treatment of gastrointestinal malignancies is challenging due to the GI tract's unique physiology. The drug's travel through the GIT segments presents a number of challenges for the local treatment when administered orally. The physiological differences between GIT segments are one of these constraints (Hasan et al., 2025). Anticancer medications may be degraded during transport to the intended tumour site due to variations in pH levels, enzyme activity, and mucus barriers within

various GIT segments. The effectiveness of treatment is hampered by variable transit durations and peristaltic movements, which further reduce the amount of time that drugs can come into contact with the tumour. Furthermore, let us say the medications are successful in getting to the intended location. In that scenario, the severe tumour microenvironment will still present some additional challenges. The tumour microenvironment is characterised by hypoxia, acidity, thick "extracellular matrix" (ECM), and efflux pumps, all of which affect medication resistance. Innovative delivery techniques are therefore crucial for boosting localised activity, extending contact time, and improving drug stability, particularly for GI malignancies, because of these various difficulties.

Additional obstacles to long-term drug administration in gastrointestinal tract include mucin and gastrointestinal epithelium turnover. Many gastrointestinal medication delivery systems involve mucoadhesion, in which dosage forms stick to the mucosa to improve absorption and extend contact duration. However, this mucoadhesion is severely limited by the turnover periods of gastrointestinal epithelium and mucin, which are 4-5 days and 1-2 days, respectively (Chu and Traverso, 2022). Finally, technologies that increase bioavailability by physical drug delivery methods, including injecting the medication directly into the insensate gastrointestinal mucosa, have also been studied. These physical technologies are limited by the thickness of the gastrointestinal tract wall. The injection depth ought to be less than the intestinal wall's thickness in order to prevent perforation. This depth can vary from approximately 1 mm in the small intestine to more than 6 mm in the restricted oesophagus.

2.9 Gap Analysis

The body of research on Targeted Drug Delivery System (TDDS) and Wireless capsule Endoscopy (WCE) integration shows encouraging advancements but also identifies important gaps, particularly in the India-Ireland region. The majority of research ignores region-specific clinical needs, the prevalence of gastrointestinal disorders, and the constraints of healthcare infrastructure in favor of solutions like magnetic actuation, controlled release, and miniaturization. There is little research on how dietary practices, patient anatomy, and GI motility vary among populations, which could affect the accuracy of drug release and capsule navigation. Some studies integrate therapeutic actuation, real-time localization, and lesion detection into a single, clinically validated platform. Furthermore, more research is required to determine scalability and cost-effective

manufacturing in resource-constrained environments. By combining India's large number of clinical cases with Irish technological know-how, cross-border cooperation between India and Ireland may fill in gaps in translational research. However, the lack of standardized evaluation procedures, patient-specific optimization techniques, and long-term biocompatibility studies prevents integrated therapeutic WCE systems from being widely used and approved by regulators.

2.10 Conclusion

This chapter highlights the convergence of Wireless Capsule Endoscopy (WCE) and Targeted Drug Delivery System (TDDS) as a promising frontier for precision GI therapies, with insights from India and Ireland shaping a global perspective. Developments in wireless power transfer, magnetic navigation, hybrid localization, and AI-driven diagnostics offer a strong technological foundation. However, integration encounters challenges in controlled actuation, precise localization, biocompatibility, and energy efficiency. Addressing these necessitates interdisciplinary innovation and clinical collaboration. By utilizing emerging engineering solutions and adapting to different healthcare scenarios, WCE-based TDDS can shift from experimental innovation to a transformative tool in GI disease management.

Chapter 3: Research Methodology

3.1 Introduction

This section represents a methodological framework for exploring expert perspectives on integrating target drug delivery mechanisms regarding WCE. This research follows quantitative research strategy that ensures methodological rigor, with this study objectives to assess benefits and barriers for using advanced precision gastrointestinal therapies.

3.2 Research philosophy

This study adopts positivism research philosophy in factual knowledge that reality is measurable, measurement and an independent approach toward research phenomenon and interpretation. According to Maretha (2023), positivism research philosophy helps to identify and explore research insights by using a structured and numerical data analysis process. This research philosophy aims to analyse scientific knowledge of scientific methods toward targeted drug delivery systems integration within healthcare sector. This philosophy depends on quantifiable observations that lead to statistical analyses within study. Based on quantifiable evidence, it ensures that research findings can be adopted and generalised to assess professional community development. In this context, this philosophical approach is important in healthcare sector's development toward using medical technology research. Hence, the healthcare sector's decisions are driven by collecting data rather than interpretive assumptions based on Wireless Capsule Endoscopy (WCE) driven drug delivery approaches. This research philosophy allows for conducting study with a highly structured format that can establish these processes of study utilisation much easier for observers.

Positivism supports use of structured survey instruments that reduce research bias and increase objectivity. Based on this philosophy, the study aligns with research principles of precision medicine, as measurable clinical outcomes are paramount within healthcare. The approach ensures that conclusions are based on verifiable data, providing healthcare stakeholders, biomedical engineers, and policymakers. These individuals have focused on establishing a solid empirical foundation for advancing precision gastrointestinal therapies through WCE-driven drug delivery innovations. Positivism research philosophy enables the research to be based on factual evidence, and not just make assumptions depending on the exploration of the research subject, unlike in the

case of interpretivism. Making predictions about the impact and adoption of WCE and targeted therapy in the field of Gastro Intestinal Tract (GIT) interventions became easier with the positivism research philosophy because it allowed to draw inferential statistical outcomes, and correlate the research variables effectively. Furthermore, it supported the use of a standardised survey process where numerical inputs delivery stood hassle free for the research participants.

3.3 Research approach

A deductive research approach has been adopted to conduct a quantitative research study to determine significance of targeted drug delivery mechanisms with Wireless Capsule Endoscopy (WCE). This research approach helps to establish theories and prior research in gastrointestinal diagnostics, medical device integration and targeted pharmacology regarding modern technological approaches. Targeted drug delivery approach and WEC have been analysed independently. Based on this research, this approach exists in a combined application toward clinical practice. According to Paynter *et al.* (2023), this approach explores importance of theoretical frameworks adaptation with analysing technological feasibility. This helps to explore importance of using biomedical engineering for increasing knowledge about anticipated benefits, including therapeutic targeting development and systematic side effects reduction. It also helps to identify potential barriers, including regulatory hurdles, biocompatibility issues, by using precision gastrointestinal therapies. Based on this approach, perceived technological complexity influences adoption willingness among medical experts toward WCE.

This method facilitates structured analysis to benchmark results against advanced medical technology adoption models. It represents actionable recommendations for future device development in clinical settings. This approach enables cause-and-effect reasoning that contributes to clinical implementation strategies and WCE technological advancements.

3.4 Research design

In this study, a descriptive research design is employed to analyse expert's perceptions for targeted drug deliberate integration mechanisms, along with Wireless Capsule Endoscopy (WCE) technology. This research design is an important factor that does not focus on variable manipulation in a detailed approach to present opportunities and issues. As per Ghanad (2023), this research design is important to explore and understand the research approach that serves in-

depth research analysis. This research design allows for collection of quantifiable characteristics, including the percentage of experts. The experts perceive WCE-based drug delivery as clinically feasible and technological issues, along with primary areas for development. It facilitates evaluating expert viewpoints into measurable trends that can emphasise industry and clinical practice. The descriptive research design has managed to systematically describe the social phenomenon. It has outlined opportunities and barriers to integrate the targeted drug delivery with WCE in the department of gastroenterology. Since the field is emerging, the use of descriptive design has assisted in generating a sense of awareness among the stakeholders, as they would further look to use experimental or longitudinal studies for a comprehensive application of targeted drug delivery with WCE.

Moreover, by using descriptive statistics to interpret quantitative survey data, this approach ensures that findings are easily interpretable by both technical and non-technical stakeholders. It is providing support for evidence-based decision-making toward precision gastrointestinal therapies technology.

3.5 Data Collection method

Based on the positivism research philosophy, deductive approach and descriptive research design, this study follows a quantitative data collection process. As per Taherdoost (2021), quantitative data collection method uses a structured online questionnaire for data gathering approaches. Based on primary data collection method, a survey has been conducted to identify the use of target drug delivery and Wireless Capsule Endoscopy (WEC) combination within the healthcare sector. Based on primary strategy, it helps to evaluate research viability, benefits and issues from research viewpoints. This research methods are appropriate for this study that allows precise measurement of current trends, variance and correlations amongst healthcare experts opinions.

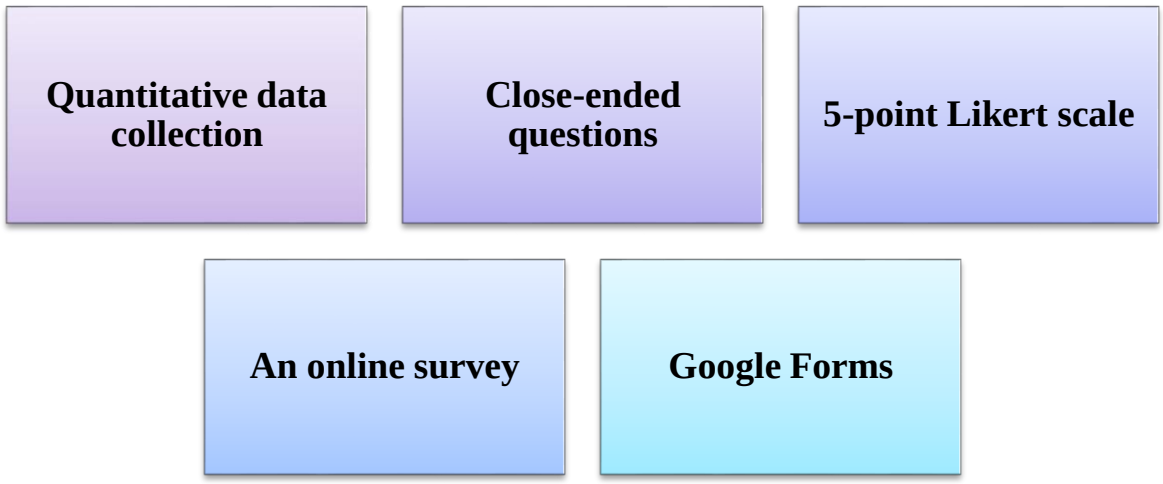

Figure 5: Data collection process

(Source: Self developed)

During this data collection, closed-ended questions and a 5-point Likert scale have been used to increase quantitative perceptions of technological readiness, feasibility, clinical benefits, with regulatory issues. According to Kotronoulas *et al.* (2023), it also enables statistical comparison and maintains consistency in data collection process and reduces subjective interpretation for this analysis. Based on primary quantitative data collection, statistical analysis correlates with lower adoption intention for technological feasibility approaches. An online survey is used to collect information by reducing professional bias. It ensures that this study's generalisable findings can be beneficial to explore clinical integration through precision gastrointestinal therapeutic technologies.

The application of quantitative data collection helps in employing numerical values derived from observations to explain and describe the phenomena (Taherdoost, 2022). In the current research, there is a need to compare the effectiveness of WCE and targeted therapy in promoting better GI interventions. Hence, the quantitative data is collected to ensure that factual evidence could back the adoption of this hybrid medical technology in the future and expand the chances of better gastrointestinal diagnosis.

The use of empirically-based survey instruments, such as validity, reliability, and quantitative analysis gives the scope to produced analytical results which share less bias and concrete evidence regarding the research constructs (Mellinger and Hanson, 2020). Similarly, the current research has used the quantitative data collection tools effectively to ensure that the research outcomes remain valid and reliable. The presence of human bias is mostly dealt with the applied sampling technique. Additionally, data consistency in the survey responses was measured as well to promote viable research outcomes. It helped determine the merit and demerit of WCE and targeted therapy in the domain of gastrointestinal diagnosis and GI therapy.

3.6 Data analysis process

The study adopted a primary quantitative method for analysing the research variables, including quantitative method. A quantitative method is adopted for analysing the research variables based on statistical and mathematical methods (Habes *et al.* 2021). Interpreting quantitative data, this study has adopted IBM SPSS software as an effective tool. Statistical methods, including mean, median, mode, standard deviation, correlation and coefficient are applied for performing the descriptive analysis of the research variables. In addition, descriptive statistics, including percentages, frequencies, can be used to evaluate perception regarding targeted drug delivery integration toward Wireless Capsule Endoscopy (WCE). In addition, inferential statistics, including chi-square tests and correlation analysis, can be used to explore relationship between research variables. Structured analytical frameworks improve knowledge about objective interpretation to make conclusions without researcher bias. Hence, these structured strategies support generalisable insights for this study. The quantitative approach has helped in determining the clinical acceptance, legal compliance, and cost structure needed to adopt a hybrid medical solution, such as WCE and targeted therapy in the field of gastroenterology.

3.7 Sampling

This study has used purposive sampling techniques based on identifying research expertise and relevance. Purposive sampling is selected for research purposes based on research qualities and traits (Hossan *et al.* 2023). This sampling approach provides insight into increasing professional knowledge toward biomedical engineering, gastrointestinal diagnostics and targeted drug delivery within healthcare sector. This research has adopted 143 sample size and targeted populations are

biomedical researchers, pharmaceutical researchers and gastroenterologists of medical devices. Hence, purposive sampling is important based on research objectives of individuals that can evaluate Wireless Capsule Endoscopy (WEC) integration with targeted drug delivery (Hossan *et al.* 2023). This sampling technique improves high-quality techniques based on research questions. It is enhancing knowledge about research findings, credibility and applicability toward technological and clinical approaches.

3.8 Reliability and validity

This research study ensures research validity and reliability to produce credible research outcomes based on clinical settings. According to William (2024), research reliability is maintained research stability and consistency measurement strategies. In increasing research reliability, research survey instruments have been employed with standardised questions based on closed-ended survey questions. Besides, a pilot test has been used to identify and refine research ambiguities. Based on this, internal consistency has been used by using Cronbach's Alpha, that improves research approaches.

Research validity ensures research development approaches toward content validity approaches. It has helped to evaluate the role of subject-matter experts in medical technology and ethics based on improving technological issues, clinical feasibility and regulatory considerations. This research approach reinforces the adaptation of technological advancements within healthcare innovation. Based on research validity, it can be used for improving knowledge for target audience within this industry. In analysing reliability and validity, it ensures research findings strategy to explore advanced precision gastrointestinal therapies. Research validity and reliability testing are important factors in conducting approach to assess research accuracy and consistency level. Cronbach's alpha is used to assess reliability and validity of proposed research work. Besides, correlation coefficient method is used to identify research validity for this data analysis process.

3.9 Ethical consideration

Ethical aspects are considered an important approach to conduct academic research strategies. This research work is concerned with using data collection through Google Forms for information gathering process. According to Sivasubramaniam *et al.* (2021), ethical integrity is used in this research process toward international and institutional guidelines. Hence, research participation

will be used as informed consent and voluntary participation for improving knowledge about data collection process. Survey respondents have been informed about research process, objectives and participation rights. Research anonymity needs to be maintained for research development strategies. Maintaining the confidentiality of the research subjects stood to be one of the major ethical dilemmas in the research. In order to ensure ethically sound research, the research subjects were notified that none of their data inputs were used for any other purpose apart from explaining the correlation between the research variables. Since the participant information sheet was also handed, it assured proper data protection and ethical compliance throughout the research.

3.10 Chapter summary

This chapter has evaluated different methodological approaches that investigate significance of expert perspectives within a clinical setting based on drug delivery mechanisms toward Wireless Capsule Endoscopy (WCE). Hence, this research adopts positivism philosophy, descriptive research design, deductive approach by using a quantitative data collection method. This methodological section has adopted a 143-sample size and calculated inferential and descriptive statistics. This research is to ensure validity, reliability and findings integrity based on research objectives.

Chapter 4: Findings and analysis

4.1 Chapter overview

The purpose of this chapter is to provide the analysis of the data that was gathered via the structured survey in order to investigate the potential, difficulties, and practicality of combining medication delivery systems with Wireless Capsule Endoscopy (WCE) technology. The purpose of this chapter is to offer a comprehensive summary of the demographic features of the respondents, as well as their professional backgrounds and their perspectives on the technical, clinical, regulatory, and commercial aspects of WCE-based drug delivery. The description of the respondents' demographic and professional characteristics, including their current area of activity, geographic location, and years of experience, is the first step in the analysis. This is followed by the presentation of descriptive data. After this, the chapter moves on to discuss responses to specific items that evaluate the feasibility of integrating drug delivery with WCE. These responses cover topics such as miniaturization, challenges involving power and batteries, sensor integration, drug formulation and stability, regulatory considerations, and collaboration between the engineering and pharmaceutical disciplines. This chapter emphasizes crucial findings and places where there are still information gaps by giving both the frequency and percentage distributions, as well as narrative interpretations of the data.

4.2 Responses and participant demographics

4.2.1 General Questions

Q1. Are you currently practicing or working in any of these positions Ireland or India?

Table 1: Current professional practice or work

Occupation	Frequency	Percent
Biomedical Engineer	63	44.1
Gastroenterologist	26	18.2
Pharmaceutical Researcher	54	37.8
Total	143	100

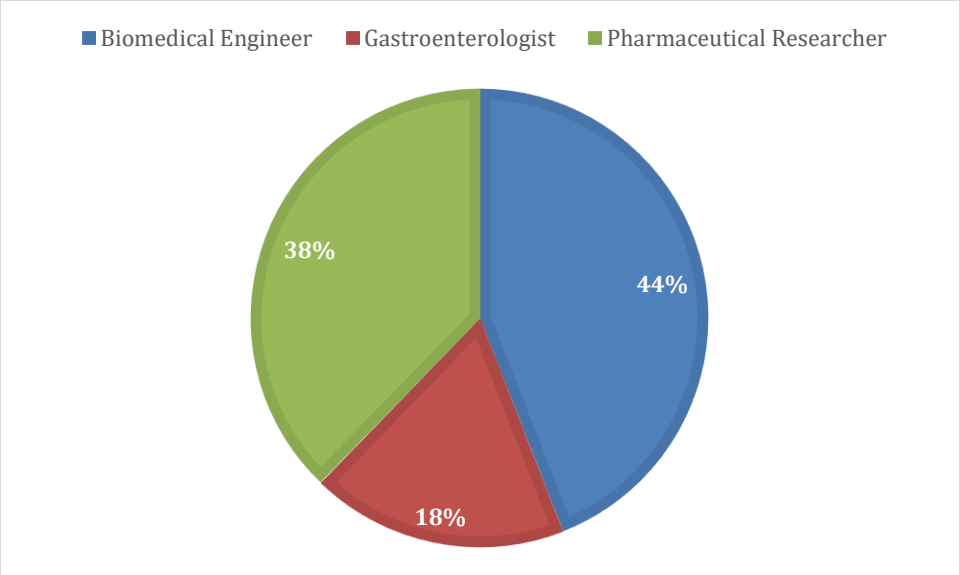

Figure 6: Current professional practice or work

Table 1 illustrates the distribution of participants according to the employment or professional activity that they are now engaged in. According to the findings, the bulk of the persons who participated in the survey are Biomedical Engineers, which accounts for 44.1% (63 individuals) of the sample. After that comes the Pharmaceutical Researchers, who make up 37.8 percent of the total consisting of 54 personnel. Gastroenterologists make up the smallest category, accounting for 18.2% of the total participants (representing 26 persons). This indicates that the results and ideas of the research are likely to reflect viewpoints predominantly from the disciplines of biomedicine and pharmaceuticals, with clinical gastroenterology making a lesser contribution. Overall, the sample exhibits a significant representation of experts from the biomedical and pharmaceutical sectors.

Q2. Which location are you currently practicing?

Table 2: Current location of professional practice

Country	Frequency	Percent
India	96	67.1
Ireland	47	32.9
Total	143	100.0

Figure 7: Current location of professional practice

The respondents' present places of professional activity are detailed in Table 2, which illustrates this information. India is home to 67.1% of the participants, which is equivalent to 96 persons. The remaining 32.9% of the participants, which is equal to 47 individuals, are situated in Ireland. There is a stronger presence of professionals from India, as shown by this distribution, which may have an impact on the overall viewpoints and replies in the survey, especially with regard to regional practices, healthcare infrastructure, and professional experiences.

Q3. How many years of professional experience do you have?

Table 3: Years of professional experience

Years of Experience	Frequency	Percent
0-5 years	81	56.6
More than 5 Years	62	43.4
Total	143	100

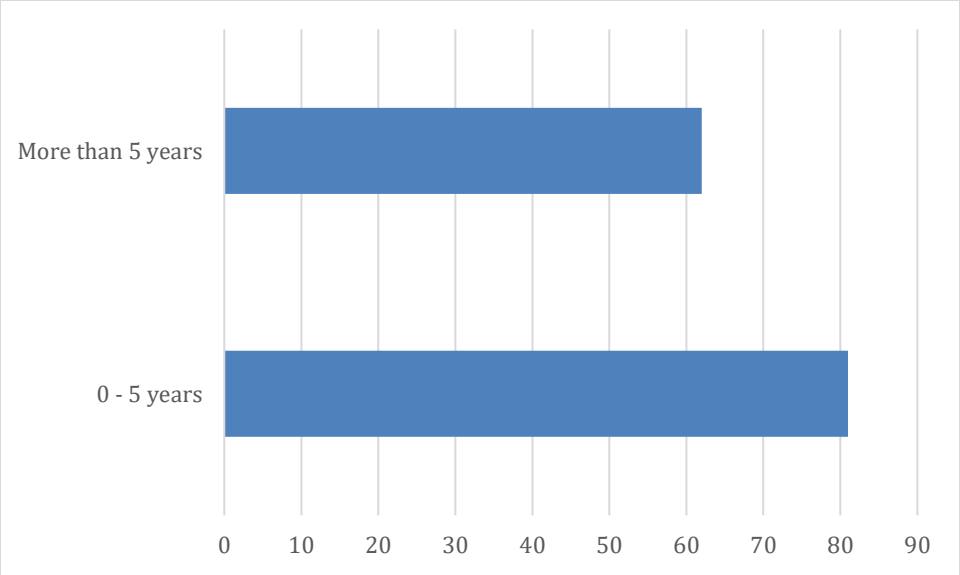

Figure 8: Years of professional experience

There is a distribution of responses in Table 3 according to the number of years of professional experience they have respectively. A comparatively younger or early-career professional group is indicated by the fact that 56.6% of the participants, or 81 persons, have 0–5 years of experience. This indicates that the majority of the participants are in their early career. On the other hand, 43.4% of the individuals, or 62 people, have more than five years of experience, which indicates that they are professionals at the middle to senior levels. Having practitioners with varying degrees of expertise in the subject allows for a more well-rounded view, since it allows for the collection of ideas from both early-career and more seasoned practitioners.

4.2.2 Section A – Biomedical Engineers

Q4. Do you think recent advancements in Wireless Capsule Endoscopy (WCE) hardware make it technically feasible to integrate a drug-delivery mechanism?

Table 4: Feasibility of integrating drug-delivery with WCE hardware

Answers	Frequency	Percent
Strongly agree	6	4.2
Agree	16	11.2
Neutral	34	23.8
Disagree	2	1.4
Strongly disagree	4	2.8
NA	81	56.6
Total	143	100.0

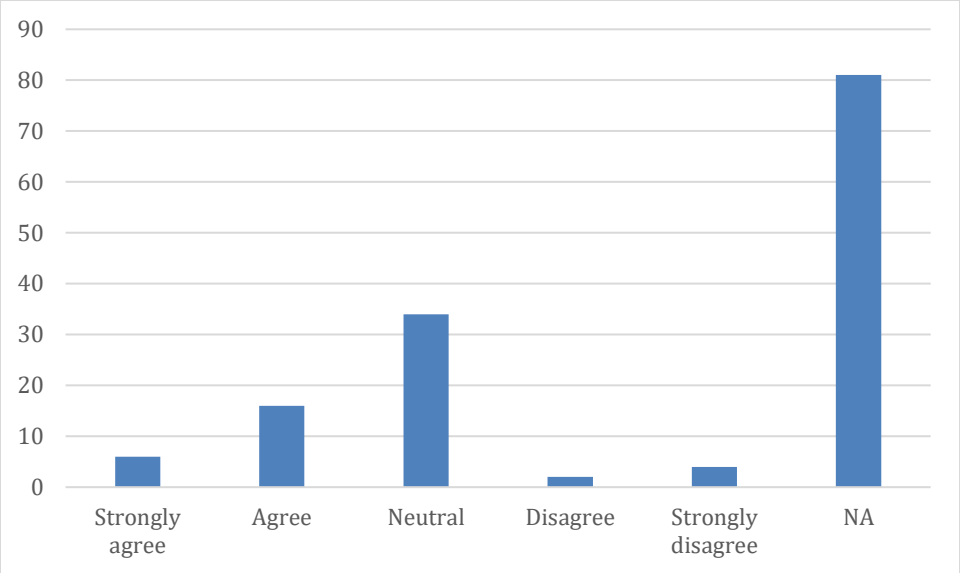

Figure 9: Feasibility of integrating drug-delivery with Wireless Capsule Endoscopy (WCE) hardware

A selection of the opinions expressed by respondents about the practicability of combining drug delivery with WCE technology is shown in Table 4. Only a tiny percentage of participants are in agreement or highly agree that such integration is conceivable (4.2%) or agree (11.2%), while

23.8% of participants are indifferent, and only a very small percentage of participants oppose (1.4%) or strongly disagree (2.8%). Particularly noteworthy is the fact that 56.6% of respondents chose the option "no answer," which indicates that more than half of the participants either do not have adequate information or expertise to evaluate the viability of this proposition. This indicates that while there is a degree of optimism over integration, a sizeable section of the sample could want further knowledge or experience with this technology before they are able to develop a judgment.

Q5. In your view, is current miniaturization and micro-actuator technology sufficient for reliable drug release inside a capsule?

Table 5: Sufficiency of miniaturization and micro-actuator technology for reliable in-capsule drug release

Answer	Frequency	Percent
Strongly agree	5	3.5
Agree	41	28.7
Neutral	14	9.8
Strongly disagree	2	1.4
NA	81	56.6
Total	143	100.0

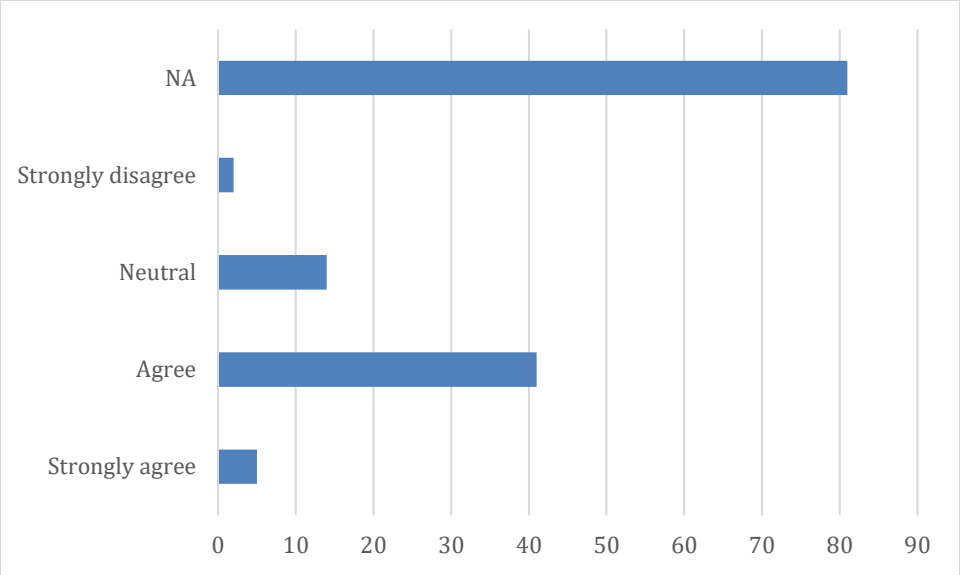

Figure 10: Sufficiency of miniaturization and micro-actuator technology for reliable in-capsule drug release

The views of the respondents are shown in Table 5, which discusses whether or not the miniaturization and micro-actuator technologies that are now available are enough for ensuring reliable in-capsule drug release. At the same time as 9.8% of respondents maintain a neutral stance and just 1.4% strongly disagree, a significant proportion of participants believe (28.7%) or strongly agree (3.5%) that these technologies should be considered appropriate. On the other hand, the majority of respondents (56.6% of them) chose "no," which indicates that they either do not have adequate knowledge or expertise in the field to assess the technical sufficiency. The fact that the sample has a limited knowledge with the precise technical features of in-capsule medication administration is highlighted by this particular fact.

Q6. Do you consider battery life and power limitations as the biggest technical challenge to adding drug delivery to Wireless Capsule Endoscopy (WCE)?

Table 6: Battery life and power limitations as the biggest technical challenge to adding drug delivery to WCE

Answer	Frequency	Percent
Strongly agree	15	10.5
Agree	28	19.6
Neutral	15	10.5
Disagree	2	1.4
Strongly disagree	2	1.4
NA	81	56.6
Total	143	100.0

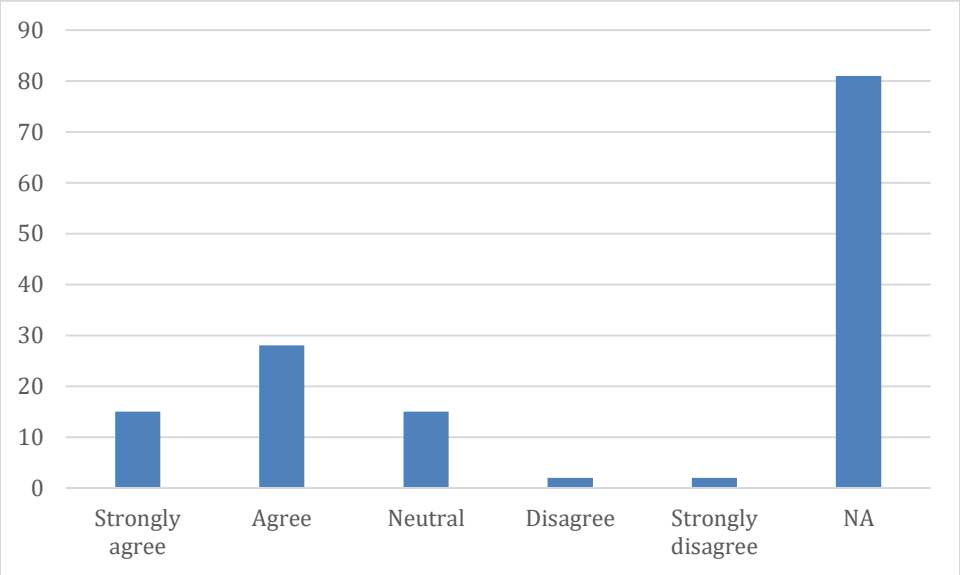

Figure 11: Battery life and power limitations as the biggest technical challenge to adding drug delivery to WCE

The respondents' assessments of the key technological obstacle for integrating medication administration into WCE are shown in Table 6. The respondents believe that the restrictions of power and battery life are the most significant. When it comes to power and battery limits, a total

of 30.1% of participants (10.5% strongly agree and 19.6% agree) perceive them to be a serious concern. A very tiny percentage of people disagree (1.4%) or strongly disagree (1.4%), whereas 10.5% of people continue to maintain their neutrality. NA (not applicable) was chosen by the majority of respondents (56.6%), suggesting that they had minimal direct experience or understanding of the technical constraints of adding medication delivery to WCE. This is similar to the responses they gave to earlier questions. In general, the replies indicate that a subgroup of respondents acknowledges power and battery constraints as a significant obstacle; nonetheless, more than half of the respondents were unable to offer an educated view.

Q7. Can current Wireless Capsule Endoscopy (WCE) sensing and communication technologies support real-time location tracking and targeted drug release?

Table 7: Current WCE sensing and communication technologies support real-time location tracking and targeted drug release

Answer	Frequency	Percent
Strongly agree	16	11.2
Agree	28	19.6
Neutral	15	10.5
Disagree	1	.7
Strongly disagree	2	1.4
NA	81	56.6
Total	143	100.0

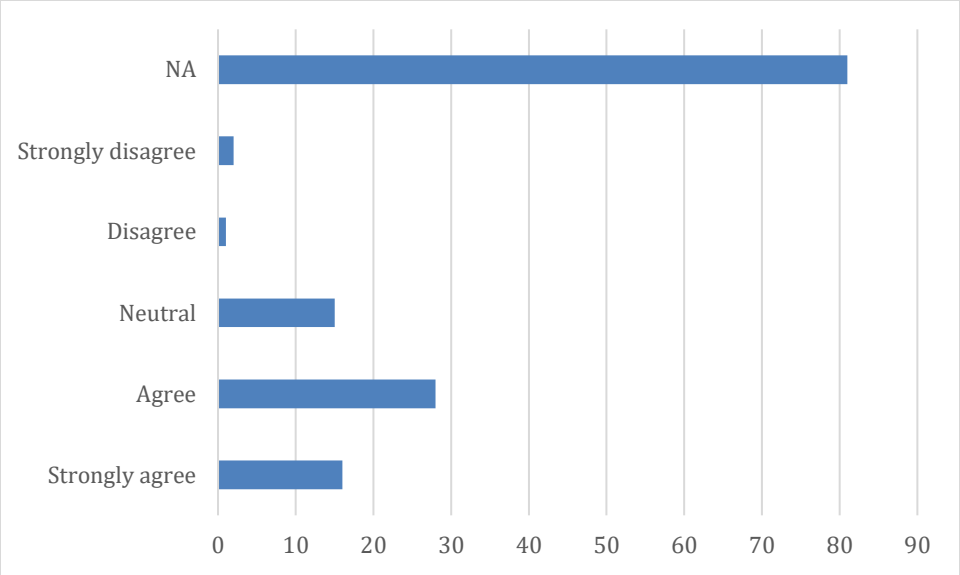

Figure 12: Current WCE sensing and communication technologies support real-time location tracking and targeted drug release

The responder's view on using current Wireless Capsule Endoscopy sensing and communication technologies support real time location tracking and targeted drug release says that 56.6 percent have chosen NA (not applicable) and 19.6 of the biomedical engineers agree to the suggestion and very low up to 0.7 disagree to this. In conclusion the majority suggest that there are no possibilities and only a minimum of 19.6 percent complies with this integration.

Q8. Do you believe adding drug reservoirs will significantly increase the manufacturing cost of Wireless Capsule Endoscopy (WCE) devices?

Table 8: Adding drug reservoirs will significantly increase the manufacturing cost of WCE devices

Answer	Frequency	Percent
Strongly agree	14	9.8
Agree	29	20.3
Neutral	15	10.5
Disagree	1	.7
Strongly disagree	3	2.1
NA	81	56.6
Total	143	100.0

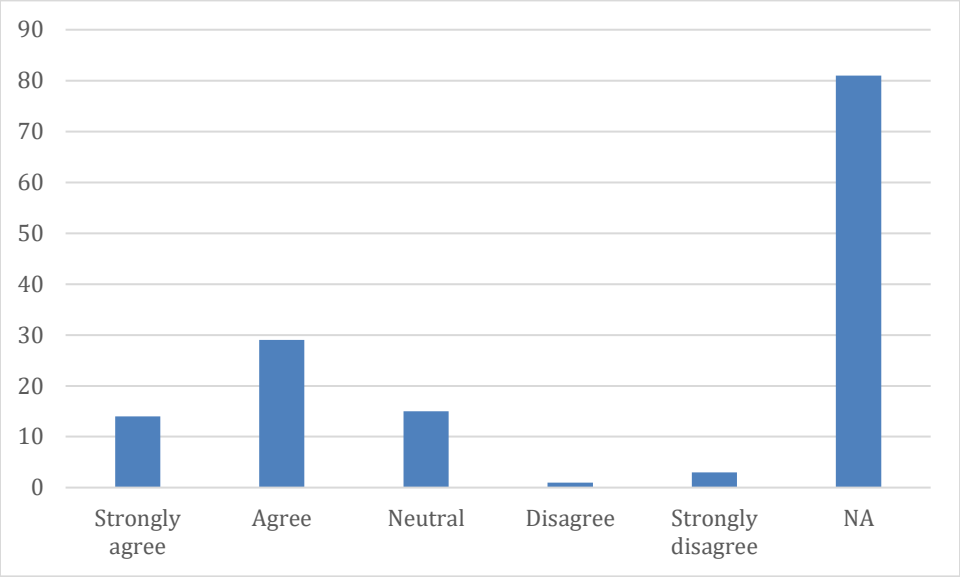

Figure 13: Adding drug reservoirs will significantly increase the manufacturing cost of WCE devices

The views of those who participated in the survey are shown in Table 8, which discusses whether or not the incorporation of drug reservoirs would considerably raise the cost of producing WCE devices. Among the participants, a total of 30.1% (9.8% strongly agree and 20.3% agree) believe that the incorporation of drug reservoirs will result in an increase in manufacturing costs. On the other hand, 10.5% of the participants maintain a neutral stance, while a tiny percentage of participants either disagree (0.7%) or strongly disagree (2.1%). Similar to the earlier issues, the majority of respondents (56.6% of them) picked "N/A," which indicates that a significant number of respondents either do not have adequate knowledge or expertise to assess the consequences of the cost. Despite the fact that a sizeable section of the sample was unable to make an informed assessment, the findings indicate that some professionals are aware of the issues over costs.

Q9. Are current biomedical engineering practices adequate to ensure biocompatibility and safe materials for an integrated capsule?

Table 9: Current biomedical engineering practices adequate to ensure biocompatibility and safe materials for an integrated capsule

Answer	Frequency	Percent
Strongly agree	12	8.4
Agree	28	19.6
Neutral	18	12.6
Disagree	2	1.4
Strongly disagree	2	1.4
NA	81	56.6
Total	143	100.0

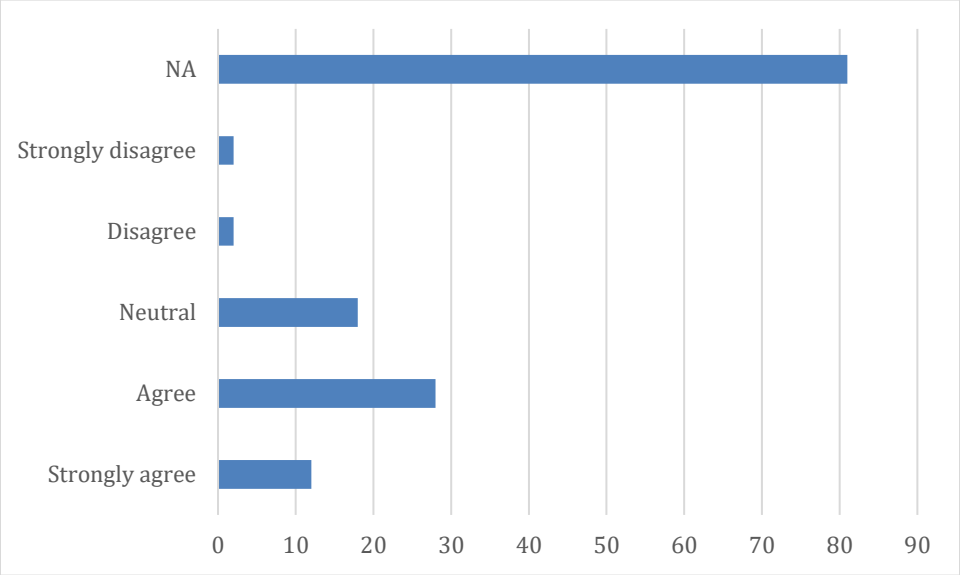

Figure 14: Current biomedical engineering practices adequate to ensure biocompatibility and safe materials for an integrated capsule

The opinions of the respondents are included in Table 9, which indicates their thoughts on whether or not the existing techniques of biomedical engineering are sufficient to guarantee biocompatibility and the use of safe materials for an integrated wireless capsule. The existing procedures are seen adequate by a total of 28% of participants, with 8.4% of them strongly agreeing and 19.6% of them agreeing. On the other hand, 12.6% of participants maintain a neutral stance, while a minor percentage of participants disagree (1.4%) or strongly disagree (1.4%). The majority of respondents, 56.6%, chose "no answer," which indicates that they have little direct knowledge or expertise in assessing the biocompatibility and material safety of such sophisticated technologies. This finding is consistent with the tables that were shown before. This demonstrates that respondents have a general lack of exposure or ambiguity about the appropriateness of the present biomedical engineering standards for integrated capsule technology.

Q10. Are current engineering collaborations with pharmaceutical partners sufficient to design a combined drug-device product?

Table 10: Current engineering collaborations with pharmaceutical partners sufficient to design a combined drug-device product

Answer	Frequency	Percent
Strongly agree	11	7.7
Agree	33	23.1
Neutral	16	11.2
Strongly disagree	2	1.4
NA	81	56.6
Total	143	100.0

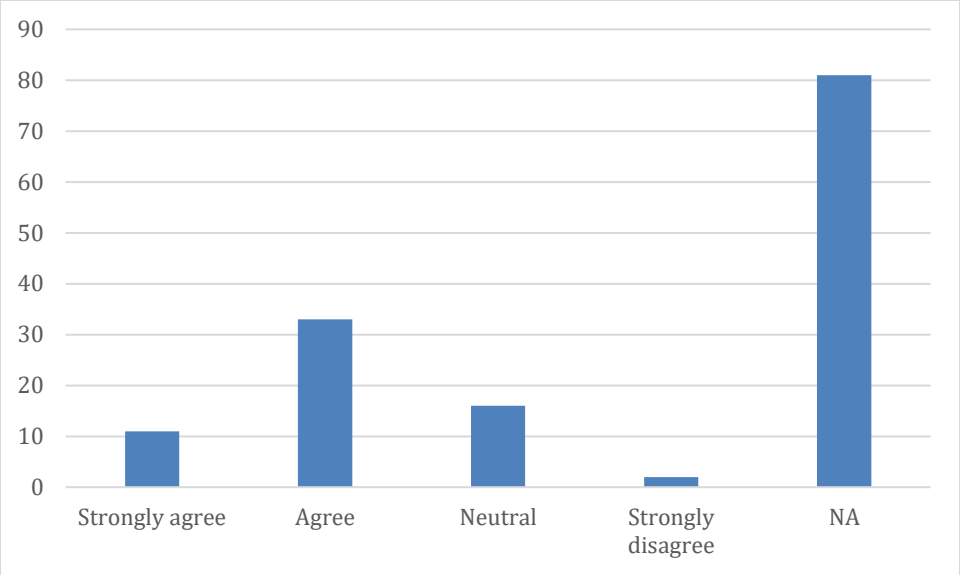

Figure 15: Current engineering collaborations with pharmaceutical partners sufficient to design a combined drug-device product

This table displays the opinions of those who participated in the survey about whether or not the engineering partnerships that are now taking place with pharmaceutical partners are enough to build a combined drug-device product. A total of 30.8% of participants, including 7.7% who strongly agree and 23.1% who agree, believe that such partnerships are appropriate. On the other hand, 11.2% of participants maintain a neutral stance, while 1.4% of participants demonstrate a strong disagreement. The majority of respondents, 56.6%, picked "no answer," which indicates that many of them do not have adequate expertise or knowledge to evaluate the efficacy of multidisciplinary cooperation. This was noted in the tables that came before this one. According to the research, while there are specialists who believe that the existing relationships represent a good opportunity, the majority of them are unable to make a decisive opinion.

Q11. Do you think regulatory requirements for combination products will require major design changes early in development?

Table 11: Regulatory requirements for combination products will require major design changes early in development

Answer	Frequency	Percent
Strongly agree	22	15.4
Agree	29	20.3
Neutral	8	5.6
Disagree	1	.7
Strongly disagree	2	1.4
NA	81	56.6
Total	143	100.0

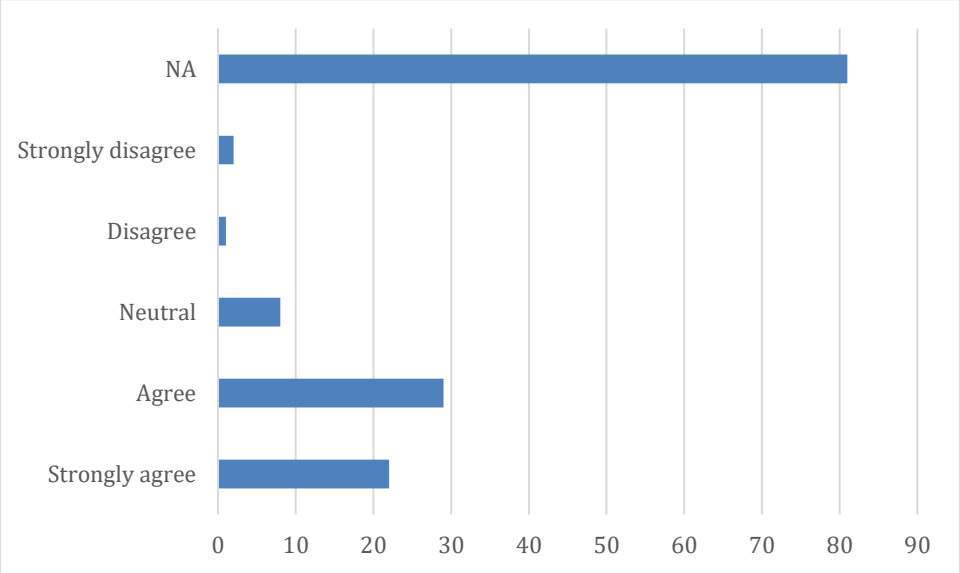

Figure 16: Regulatory requirements for combination products will require major design changes early in development

Table 11, the views of the respondents are shown about whether or not the regulatory requirements for combination goods would need significant design changes at an early stage in the development process. A total of 35.7% of participants, including 15.4% who strongly agree and 20.3% who agree, are of the opinion that regulatory limits would have a substantial influence on early design

choices. On the other hand, 5.6% say they have no opinion, while a minor percentage of individuals either disagree (0.7%) or strongly disagree (1.4%). The majority of respondents, 56.6%, responded "no," which indicates that they have minimal direct experience or understanding of the regulatory implications for combination drug-device products. This information is consistent with the results of earlier research. Despite the fact that more than half of the respondents were unable to offer an educated judgment, these findings indicate that regulatory concerns are considered by a subgroup of respondents to be a potentially essential aspect in the development process.

Q12. How likely is your organisation to develop an integrated Wireless Capsule Endoscopy (WCE) with drug delivery prototype within the next 3 years?

Table 12: Likelihood of developing an integrated WCE with drug delivery prototype within the next 3 years

Answer	Frequency	Percent
Very likely	8	5.6
Likely	34	23.8
Neutral	17	11.9
Unlikely	1	.7
Very unlikely	2	1.4
NA	81	56.6
Total	143	100.0

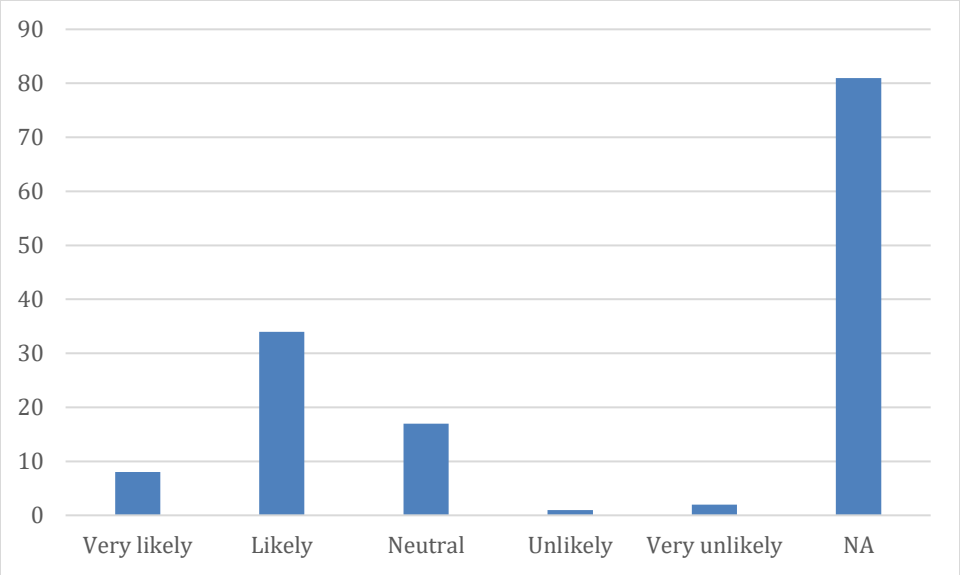

Figure 17: Likelihood of developing an integrated wireless capsule endoscopy with drug delivery prototype within the next 3 years

In Table 12, the opinions of those who participated in the survey on the possibility of the development of an integrated WCE equipment that is capable of drug delivery within the next three years. 29.4% of participants, including 5.6% extremely likely and 23.8% probable, believe that such a development is achievable within this period. On the other hand, 11.9% of participants maintain a neutral stance, while a very tiny fraction of participants is either very unlikely (1.4% or very unlikely) or very unlikely (0.7%). The majority of respondents, 56.6%, picked "N/A," which indicates that more than half of the respondents do not believe they have adequate information or insight to evaluate the near-term growth prospects. This is similar to the situation that was found in the tables that came before it. Based on the findings, it seems that some of the respondents have a cautious optimism, which is tempered by a significant amount of uncertainty.

4.2.3 Section B – Gastroenterologist

Q13. Would a Wireless Capsule Endoscopy (WCE) with targeted drug delivery improve patient outcomes for conditions such as Inflammatory Bowel Disease and small bowel disease?

Table 13: Impact of WCE with targeted drug delivery on patient outcomes for inflammatory bowel disease and small bowel disease

Answer	Frequency	Percent
Strongly agree	6	4.2
Agree	9	6.3
Neutral	10	7.0
NA	118	82.5
Total	143	100.0

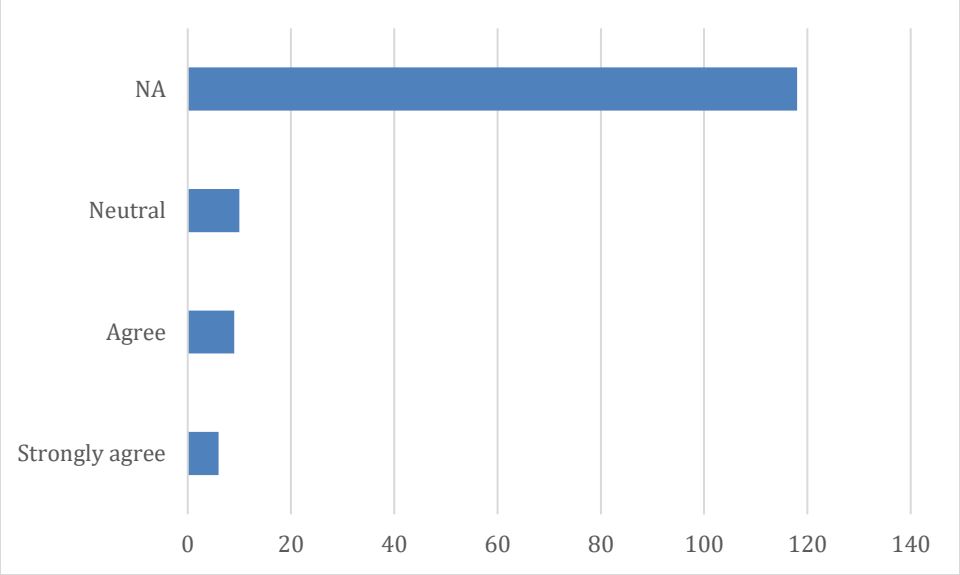

Figure 18: Impact of WCE with targeted drug delivery on patient outcomes for inflammatory bowel disease and small bowel disease

The perspectives of the respondents are shown in Table 13, which discusses the possible influence that WCE with targeted medicine administration might have on the outcomes of patients suffering from inflammatory bowel disease and small bowel disease. 4.2% of participants are in complete agreement or agreement with the statement that WCE with medication administration might

enhance patient outcomes, while 7.0% of participants are indifferent on the matter. Particularly noteworthy is the fact that the vast majority of respondents (82.5% of them) chose the null option, which indicates that the majority of respondents do not believe they have adequate knowledge or expertise to evaluate the clinical effect of this technology. A large knowledge gap regarding the therapeutic uses of integrated WCE devices is highlighted by this fact among the specialists who were polled.

Q14. Could Wireless Capsule Endoscopy (WCE) based drug delivery reduce the need for repeated invasive endoscopies or systemic treatments?

Table 14: Wireless Capsule Endoscopy-based drug delivery reduces the need for repeated invasive endoscopies or systemic treatments

Answer	Frequency	Percent
Strongly agree	6	4.2
Agree	17	11.9
Neutral	2	1.4
NA	118	82.5
Total	143	100.0

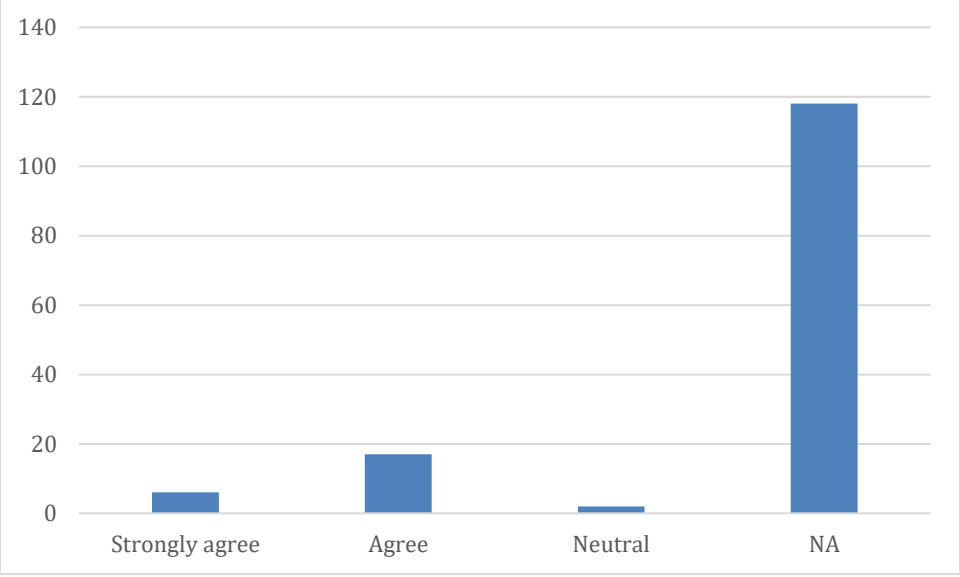

Figure 19: WCE-based drug delivery reduces the need for repeated invasive endoscopies or systemic treatments

The responses of the respondents are shown in Table 14, which indicates their perspectives about whether or not medication administration by WCE might eliminate the requirement for recurrent invasive endoscopies or systemic therapies. A total of 16.1% of participants, including 4.2% who strongly agree and 11.9% who agree, are of the opinion that WCE-based medication administration may reduce the need for conventional procedures or systemic therapy. At the same time, 1.4% of participants are of the opinion that they are indifferent. The great majority of respondents, which accounts for 82.5% of the total, chose NA (not applicable), which indicates that the majority of respondents do not possess adequate information or clinical expertise to assess the likely advantages of this strategy. According to this, it seems that the professionals who were polled had a limited understanding and familiarity with the practical therapeutic effect of WCE-integrated medication administration.

Q15. Do you think patient acceptance would be high for a drug-delivering capsule compared to pills or injections?

Table 15: Patient acceptance would be high for a drug-delivering capsule compared to pills or injections

Answer	Frequency	Percent
Strongly agree	10	7.0
Agree	11	7.7
Neutral	4	2.8
NA	118	82.5
Total	143	100.0

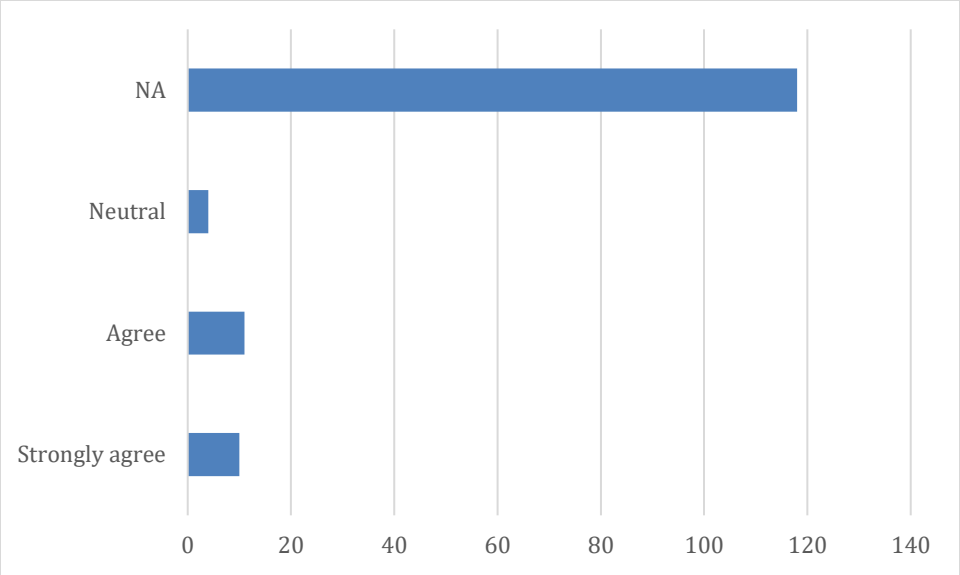

Figure 20: Patient acceptance would be high for a drug-delivering capsule compared to pills or injections

The perspectives of the respondents on the acceptability of a drug-delivering capsule by patients in comparison to the acceptance of traditional tablets or injections are shown in Table 15. A total of 14.7% of participants, including 7.0% participants who strongly agree and 7.7% participants who agree, are of the opinion that patients would prefer the capsule-based strategy, while 2.8% of people are indifferent. This indicates that there is insufficient information or expertise in forecasting patient preferences for this unique medication delivery technology. The vast majority of respondents (82.5%) picked an answer that was not applicable. In light of this, it seems that while some experts predict a greater level of patient acceptability, the majority of them are unable to offer a firm judgment on the reaction of patients.

Q16. Would concerns about capsule retention or device-related complications limit adoption in clinical practice?

Table 16: Concerns about capsule retention or device-related complications limit adoption in clinical practice

Answer	Frequency	Percent
Strongly agree	6	4.2
Agree	14	9.8
Neutral	5	3.5
NA	118	82.5
Total	143	100.0

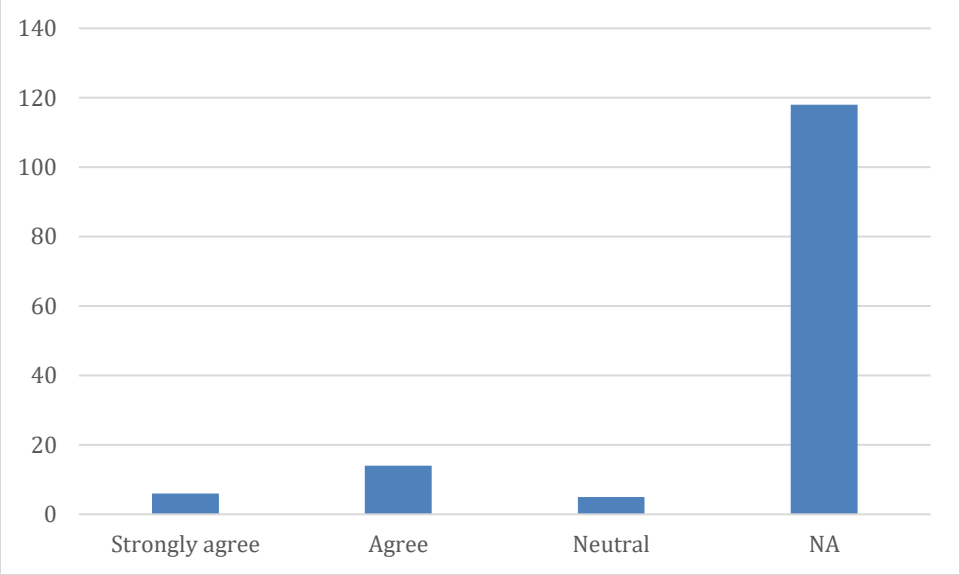

Figure 21: Concerns about capsule retention or device-related complications limit adoption in clinical practice

In Table 16, the opinions of the respondents are shown on the question of whether or not concerns about capsule retention or difficulties linked to the device might potentially hinder the use of drug-delivering capsules in clinical practice. These safety issues are seen as possible obstacles by a total of 14.0% of participants, with 4.2% of them strongly agreeing and 9.8% of them agreeing. However, 3.5% of participants remain indifferent. It is clear that the majority of respondents do

not have adequate clinical expertise or knowledge to assess the influence of such hazards on adoption, as shown by the fact that the great majority of respondents (82.5%) picked this choice. In light of this, it seems that a subset of experts acknowledges the existence of safety problems; yet, the general level of expertise with dangers associated with devices continues to be restricted.

Q17. For which condition would drug-delivering Wireless Capsule Endoscopy be most clinically useful?

Table 17: Most clinically useful condition for drug-delivering WCE

Answer	Frequency	Percent
Combining diagnosis and treatment in one procedure	1	0.7
Local infection / antimicrobial delivery	9	6.3
Localised inflammatory lesions	7	4.9
Post-surgical site therapy	3	2.1
Tumour-directed therapy (small bowel)	5	3.5
NA	118	82.5
Total	143	100.0

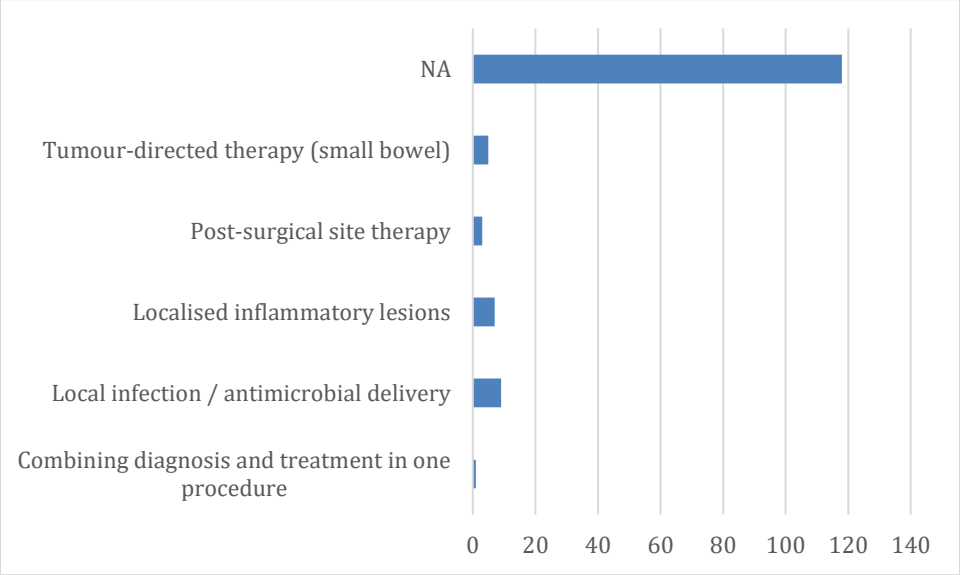

Figure 22: Most clinically useful condition for drug-delivering WCE

For the purpose of determining the most clinically relevant situation for drug-delivering WCE, the views of the respondents are shown in Table 17. The following specific applications were identified by a small percentage of the population: local infection/antimicrobial delivery (6.3%), localized inflammatory lesions (4.9%), tumor-directed therapy in the small bowel (3.5%), post-surgical site therapy (2.1%), and combining diagnosis and treatment in a single procedure (0.7%). NA (not applicable) was picked by an overwhelming majority of respondents (82.5%), which indicates that the majority of respondents do not have adequate knowledge or clinical expertise to identify the most significant therapeutic applications for WCE-based drug delivery. This demonstrates that there is a significant lack of understanding or familiarity with the condition-specific applications of one of these developing technologies.

Q18. Would the ability to diagnose and deliver drugs simultaneously in one procedure streamline patient care?

Table 18: Ability to diagnose and deliver drugs simultaneously in one procedure streamline patient care

Answer	Frequency	Percent
Strongly agree	4	2.8
Agree	7	4.9
Neutral	14	9.8
NA	118	82.5
Total	143	100.0

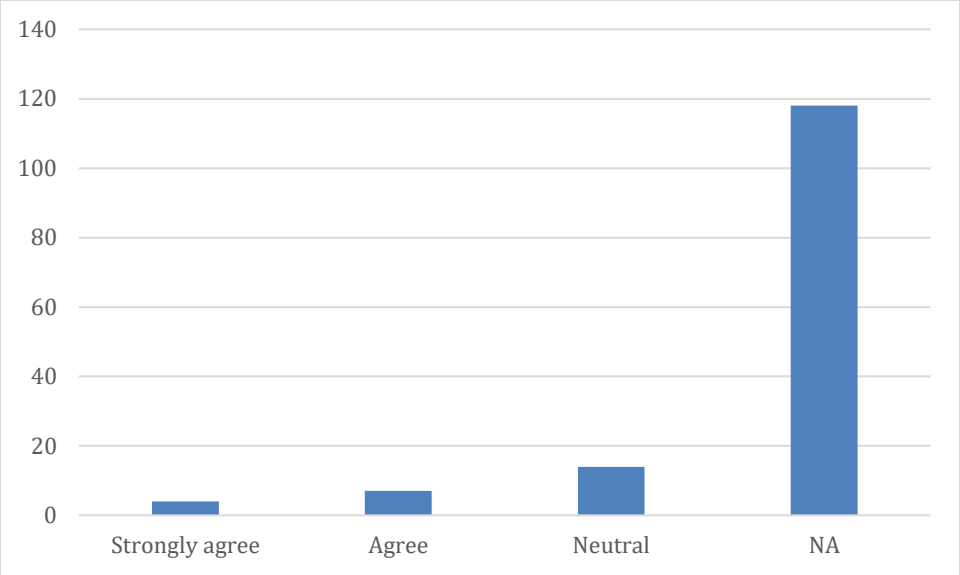

Figure 23: Ability to diagnose and deliver drugs simultaneously in one procedure streamline patient care

The opinions of those who participated in the survey are shown in Table 18, which discusses whether or not the capability to diagnose and administer medications concurrently during a single operation might simplify the process of providing medical treatment to patients. A total of 7.7% of participants, including 2.8% who strongly agree and 4.9% who agree, consider this skill to be advantageous, while 9.8% of participants maintain a neutral stance. It is clear that the great majority of respondents do not believe they have adequate knowledge or clinical expertise to evaluate the possible influence on patient care, as shown by the fact that 82.5% of them picked "Nationally Not Applicable." This indicates that there is a limited familiarity with the practical benefits of merging diagnostic and therapeutic activities into a single wireless capsule technique.

Q19. How extensive do you think the training requirements would be for gastroenterologists to use Wireless Capsule Endoscopy (WCE) -based drug delivery?

Table 19: Extent of training requirements for gastroenterologists to use WCE-based drug delivery

Answer	Frequency	Percent
Extensive	3	2.1
Significant	14	9.8
Moderate	6	4.2
Slight	2	1.4
NA	118	82.5
Total	143	100.0

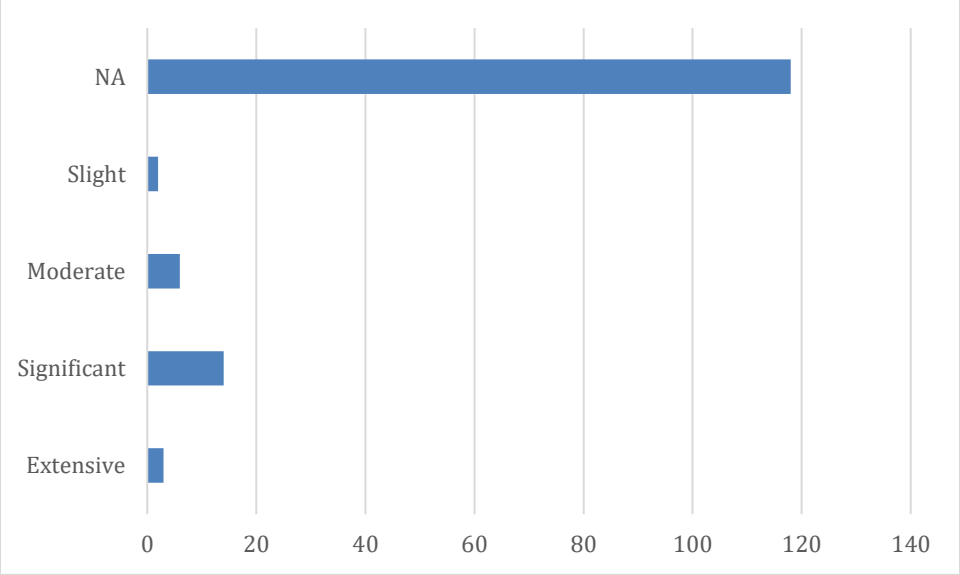

Figure 24: Extent of training requirements for gastroenterologists to use wireless capsule endoscopy-based drug delivery

The responses of the respondents are shown in Table 19, which details their thoughts about the amount of the training needed for gastroenterologists to adopt wireless capsule endoscopy (WCE)-based medication delivery. The overall number of participants who feel that considerable training would be required is 16.1% (2.1% extensive, 9.8% major, and 4.2% moderate). On the other hand,

1.4% of participants believe that there is just a modest demand on their part. With respect to the training requirements for adopting WCE-based medication administration in clinical practice, the majority of respondents (82.5%) picked NA (not applicable), which indicates that they have little knowledge or expertise in this area. Taking everything into consideration, the results indicate that while some individuals foresee significant training needs, the majority of respondents are unable to make a firm evaluation.

Q20. Do you consider reimbursement and patient cost, a major barrier to adoption?

Table 20: Reimbursement and patient cost as a barrier to adoption

Answer	Frequency	Percent
Yes	19	13.3
No	3	2.1
Not sure	3	2.1
NA	118	82.5
Total	143	100.0

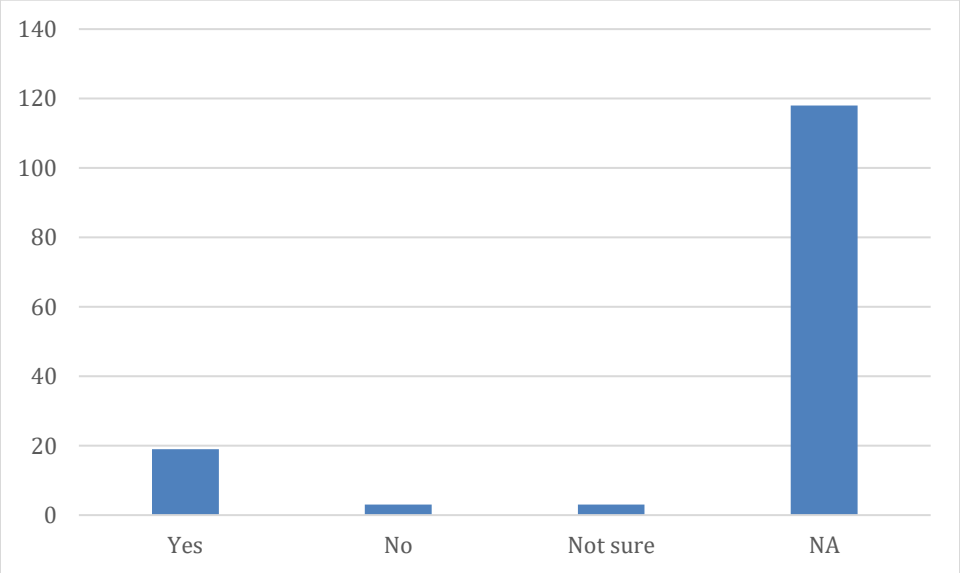

Figure 25: Reimbursement and patient cost as a barrier to adoption

The opinions of those who participated in the survey are shown in Table 20, which discusses whether or not reimbursement and patient cost might be considered potential obstacles to the implementation of WCE-based medication delivery. With regard to adoption, a total of 13.3% of participants are of the opinion that cost and reimbursement concerns would be a barrier, while 2.1% of participants are of the opinion that they would not be, and another 2.1% are unsure. The majority of respondents believe that they do not have adequate knowledge or expertise to evaluate the financial hurdles to implementation, as shown by the fact that the majority of respondents (82.5%) picked NA (not applicable). In light of this, it seems that while a minority of the sample acknowledges the possibility of cost being a role, the overall awareness of economic concerns in WCE adoption is generally low.

Q21. If proven safe and effective, how likely would you be to adopt Wireless Capsule Endoscopy (WCE) with targeted drug delivery within 5 years?

Table 21: Likelihood of adopting WCE with targeted drug delivery within 5 years

Answer	Frequency	Percent
Very likely	3	2.1
Likely	18	12.6
Neutral	4	2.8
NA	118	82.5
Total	143	100.0

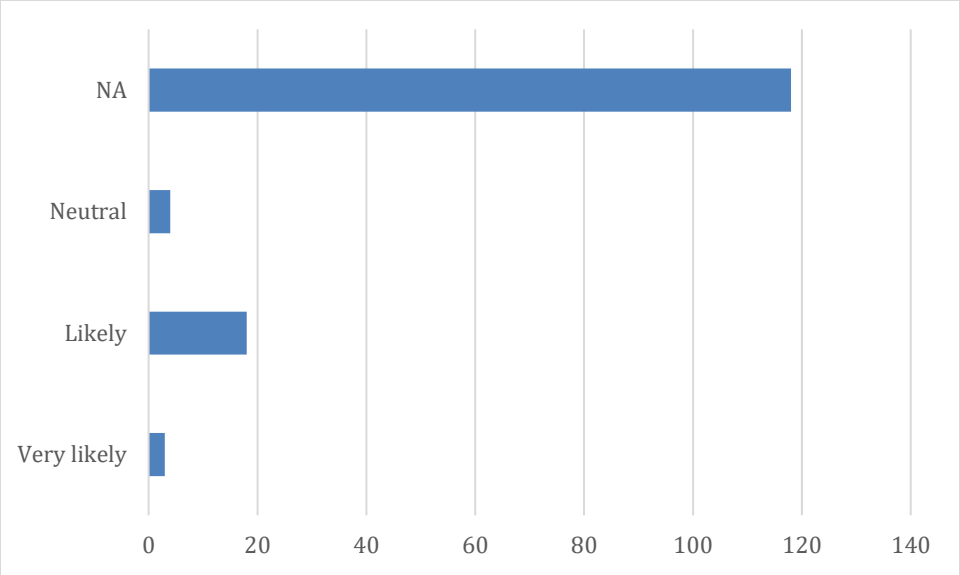

Figure 26: Likelihood of adopting wireless capsule endoscopy with targeted drug delivery within 5 years

The views of the respondents on the probability of implementing wireless capsule endoscopy (WCE) with targeted medicine delivery over the next five years are shown in Table 21. There is a total of 14.7% of participants who regard adoption to be plausible during this period, with 2.8% remaining neutral. This may be broken down as follows: 2.1% highly likely and 12.6% likely. 82.5% of respondents chose the option "no answer," which indicates that the majority of respondents do not believe they have adequate knowledge or expertise to forecast adoption patterns. The findings, taken as a whole, indicate that a small subgroup of respondents are cautiously optimistic, while the larger sample is marked by severe uncertainty.

Section C – Pharmaceutical Researchers

Q22. Do you believe delivering drugs via Wireless Capsule Endoscopy (WCE) could improve local therapeutic efficacy compared to systemic dosing?

Table 22: Delivering drugs via WCE could improve local therapeutic efficacy compared to systemic dosing

Answer	Frequency	Percent
Strongly agree	6	4.2
Agree	22	15.4
Neutral	21	14.7
Disagree	3	2.1
NA	91	63.6
Total	143	100.0

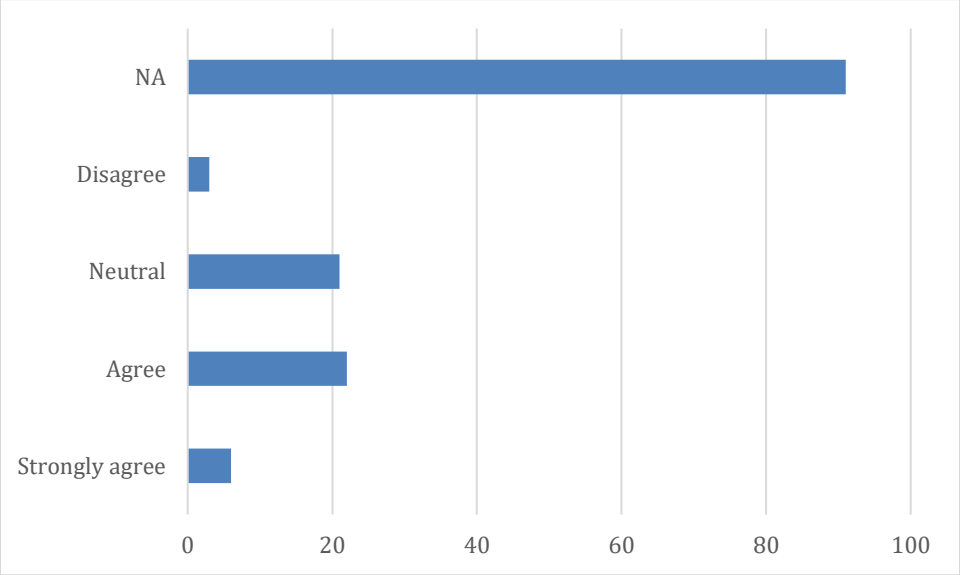

Figure 27: Delivering drugs via WCE could improve local therapeutic efficacy compared to systemic dosing

When compared to systemic dosing, the opinions of respondents are shown in Table 22 about whether or not the delivery of pharmaceuticals by WCE might better enhance the local therapeutic effectiveness. In all, 19.6% of participants are of the opinion that targeted medication

administration may improve the results of local therapy, with 4.2% of them highly agreeing and 15.4% of them agreeing. On the other hand, 14.7% of people are indifferent, and 2.1% of them disagree. Indicating that many respondents do not believe they have the knowledge or clinical expertise to assess the therapeutic benefits of WCE-based drug delivery, the majority of respondents (63.6% of them) picked the option Not Applicable. According to these findings, not only do some experts acknowledge the possibility of effectiveness gains, but there is a general lack of familiarity with this technique.

Q23. Can current pharmaceutical technologies formulate drugs that are stable and effective for capsule-mediated delivery?

Table 23: Current pharmaceutical technologies formulate drugs that are stable and effective for capsule-mediated delivery

Answer	Frequency	Percent
Strongly agree	12	8.4
Agree	32	22.4
Neutral	7	4.9
Disagree	1	.7
NA	91	63.6
Total	143	100.0

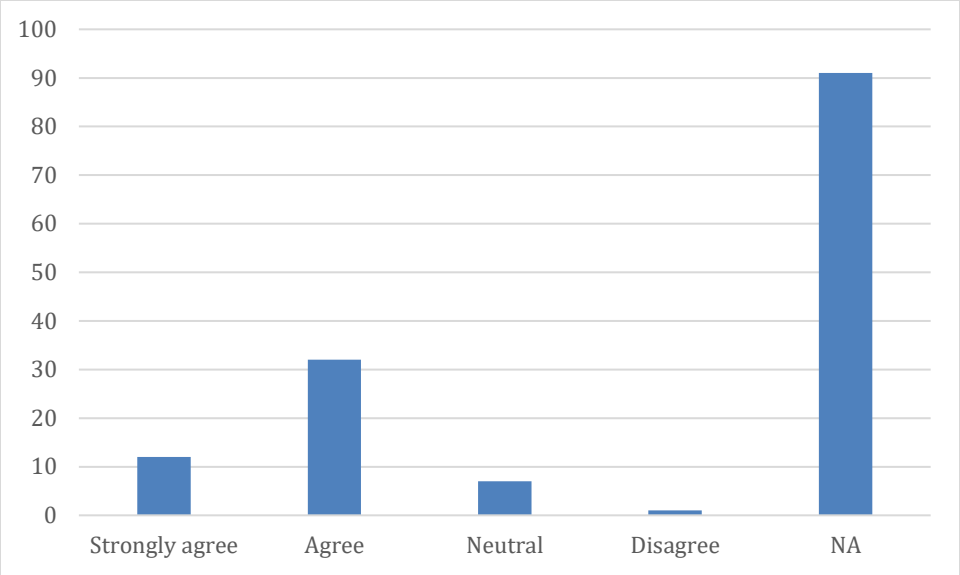

Figure 28: Current pharmaceutical technologies formulate drugs that are stable and effective for capsule-mediated delivery

Regarding the question of whether or not the pharmaceutical technologies that are now available can create pharmaceuticals that are stable and effective for capsule-mediated delivery, the views of the respondents are shown in Table 23. 30.8% of participants, including 8.4% who strongly agree and 22.4% who agree, are of the opinion that the technologies that are now available are capable of facilitating successful capsule-based medication administration. On the other hand, 4.9% of participants are indifferent and 0.7% of participants disagree. Indicating that many respondents do not believe they have the knowledge or expertise to evaluate the stability and efficacy of medications that are prepared for capsule-mediated administration, the majority of respondents (63.6% of them) picked the option which was not applicable. It seems from this that while there are experts who are confident in the capabilities of the pharmaceutical industry at the present time, there is still a general lack of knowledge with capsule-specific medication formulation.

Q24. Is ensuring drug stability in varying gastric and intestinal pH levels a major challenge for Wireless Capsule Endoscopy (WCE) drug delivery?

Table 24: Ensuring drug stability in varying gastric and intestinal pH levels a major challenge for WCE drug delivery

Answer	Frequency	Percent
Strongly agree	17	11.9
Agree	19	13.3
Neutral	15	10.5
Strongly disagree	1	.7
NA	91	63.6
Total	143	100.0

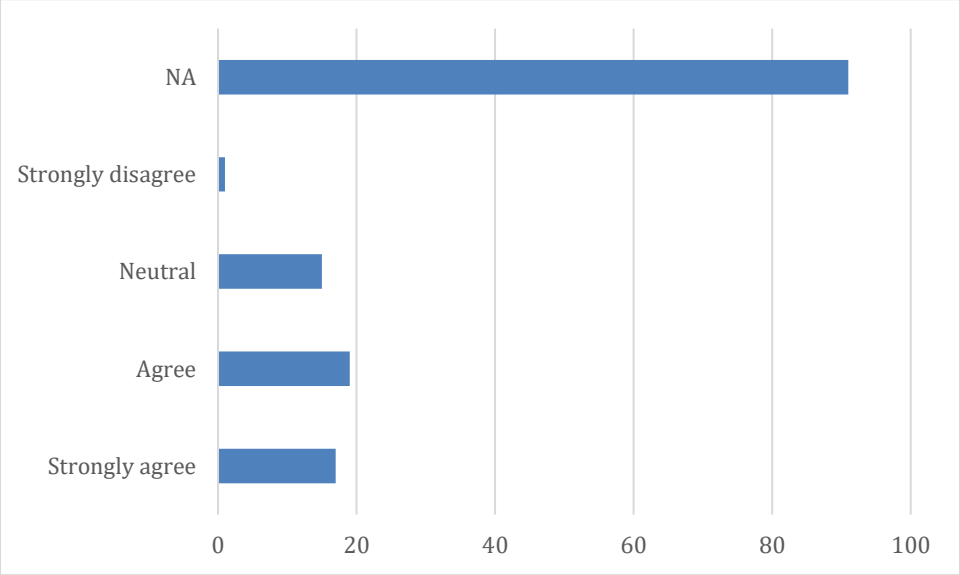

Figure 29: Ensuring drug stability in varying gastric and intestinal pH levels a major challenge for WCE drug delivery

In Table 24, we show the opinions of those who participated in the survey about whether or not guaranteeing drug stability at different pH levels in the stomach and the intestinal tract is a significant obstacle for WCE drug delivery. Among the participants, a total of 25.2% perceive medication stability throughout gastrointestinal settings to be a substantial difficulty. Of those

individuals, 11.9% strongly agree and 13.3% agree with this statement. On the other hand, 10.5% stay neutral, and 0.7% strongly disagree. It was indicated that there was minimal understanding or expertise with the formulation and delivery problems that are special to WCE-based medication delivery, since the majority of respondents (63.6% of them) picked N/A. Based on these findings, it seems that while a certain group of specialists acknowledges pH-related stability as a significant technical problem, the general level of acquaintance with this matter continues to be low.

Q25. Would integrating sensors into Wireless Capsule Endoscopy (WCE) to detect local environment (e.g., pH, biomarkers) be useful for precise drug release?

Table 25: Integrating sensors into WCE to detect local environment (e.g., pH, biomarkers) be useful for precise drug release

Answer	Frequency	Percent
Strongly agree	13	9.1
Agree	21	14.7
Neutral	16	11.2
Disagree	2	1.4
NA	91	63.6
Total	143	100.0

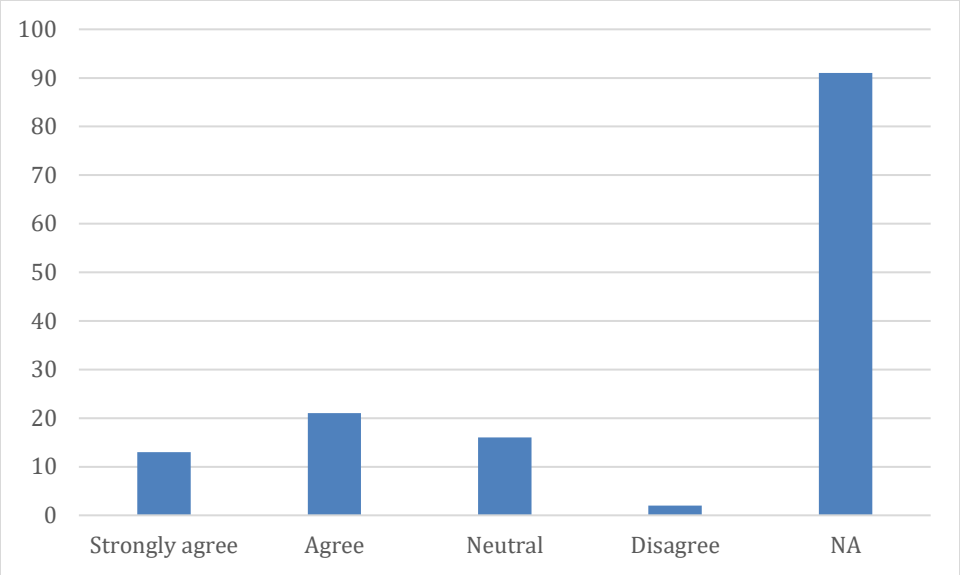

Figure 30: Integrating sensors into WCE to detect local environment (e.g., pH, biomarkers) be useful for precise drug release

The perspectives of the respondents are shown in Table 25 about the possibility of incorporating sensors into WCE in order to detect local environmental parameters (such as pH and biomarkers) for the purpose of achieving exact drug release. In total, 23.8% of participants (9.1% strongly agree and 14.7% agree) are of the opinion that the integration of such sensors will improve the delivery of drugs to specific locations. On the other hand, 11.2% of participants are indifferent and 1.4% of participants disagree. 63.6% percent of respondents said "no," which indicates that they have minimal understanding or expertise with sensor-enabled WCE technology. According to these data, while there are specialists who are aware of the potential advantages of environmental sensing for precise medication release, there is still a general lack of knowledge with these sophisticated technological skills.

Q26. Do you think manufacturing and quality-control processes for combined drug-device products will be more complex than device-only or drug-only products?

Table 26: Manufacturing and quality-control processes for combined drug-device products will be more complex than device-only or drug-only products

Answer	Frequency	Percent
Strongly agree	14	9.8
Agree	22	15.4
Neutral	14	9.8
Disagree	1	.7
Strongly disagree	1	.7
NA	91	63.6
Total	143	100.0

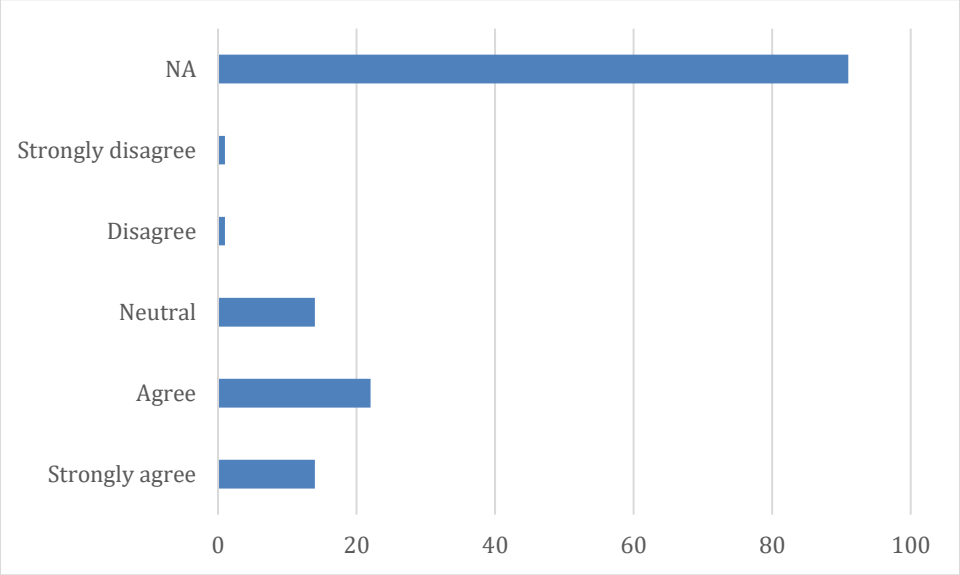

Figure 31: Manufacturing and quality-control processes for combined drug-device products will be more complex than device-only or drug-only products

The impressions of the respondents about the complexity of the manufacturing and quality-control procedures for combination drug-device goods are shown in Table 26, which compares these processes to those for device-only or drug-only products. 25.2% of participants, including 9.8% who strongly agree and 15.4% who agree, are of the opinion that the production of integrated

goods is more complicated. On the other hand, 9.8% of participants are indifferent, while a very tiny number of participants disagree (0.7%) or strongly disagree (0.7%). There was a lack of understanding or expertise with the manufacturing and quality-control difficulties that are special to drug-device combination products, as indicated by the majority of respondents (63.6%), who picked "as not applicable." In general, the replies indicate that a certain group of experts intends to expect an increase in the complexity of manufacturing, however the majority of them are unable to make a final judgment.

Q27. Can clinical pharmacokinetics of drug release from capsules be reliably measured and validated in trials?

Table 27: Clinical pharmacokinetics of drug release from capsules be reliably measured and validated in trials

Answer	Frequency	Percent
Strongly agree	14	9.8
Agree	25	17.5
Neutral	12	8.4
Disagree	1	.7
NA	91	63.6
Total	143	100.0

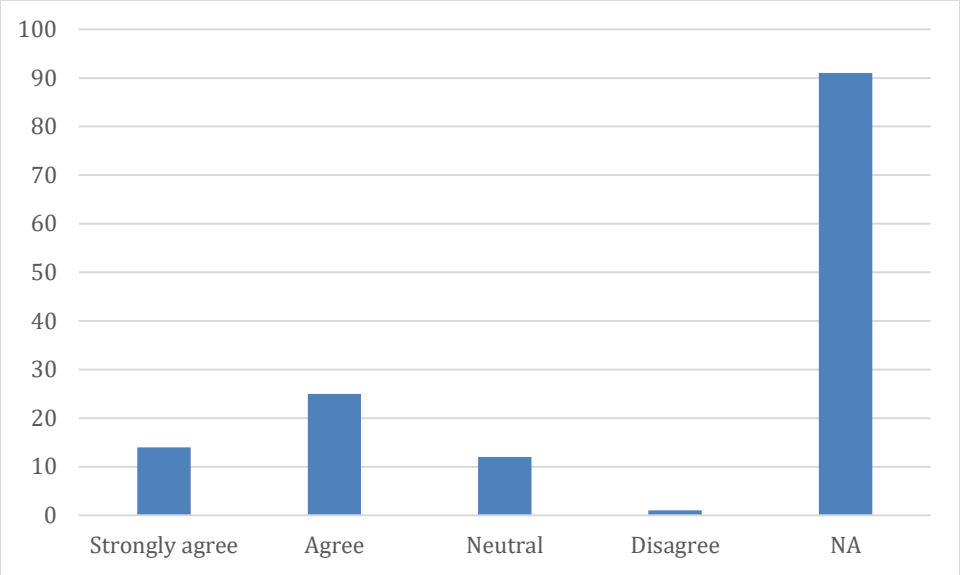

Figure 32: Clinical pharmacokinetics of drug release from capsules be reliably measured and validated in trials

According to the opinions expressed by the respondents, the clinical pharmacokinetics of drug release from capsules may be reliably assessed and confirmed in clinical studies. These opinions are shown in Table 27. There is a consensus among the participants that pharmacokinetic measurements and validations are achievable, with 27.3% of them believing that this is the case (9.8% strongly agreeing and 17.5% agreeing), while 8.4% of them are indifferent and 0.7% disagree. In terms of the clinical assessment of capsule-based medication release, the majority of respondents (63.6% of them) picked NA (not applicable), which indicates that they have insufficient expertise or understanding in this area. According to these data, while there are specialists who are confident in their capacity to evaluate pharmacokinetics in clinical trials, the majority of respondents are unable to give a statement that can be considered conclusive.

Q28. Is collaboration between pharmaceutical companies and medical device manufacturers essential for this technology's success?

Table 28: Collaboration between pharmaceutical companies and medical device manufacturers essential for this technology success

Answer	Frequency	Percent
Strongly agree	20	14.0
Agree	25	17.5
Neutral	5	3.5
Disagree	1	.7
Strongly disagree	1	.7
NA	91	63.6
Total	143	100.0

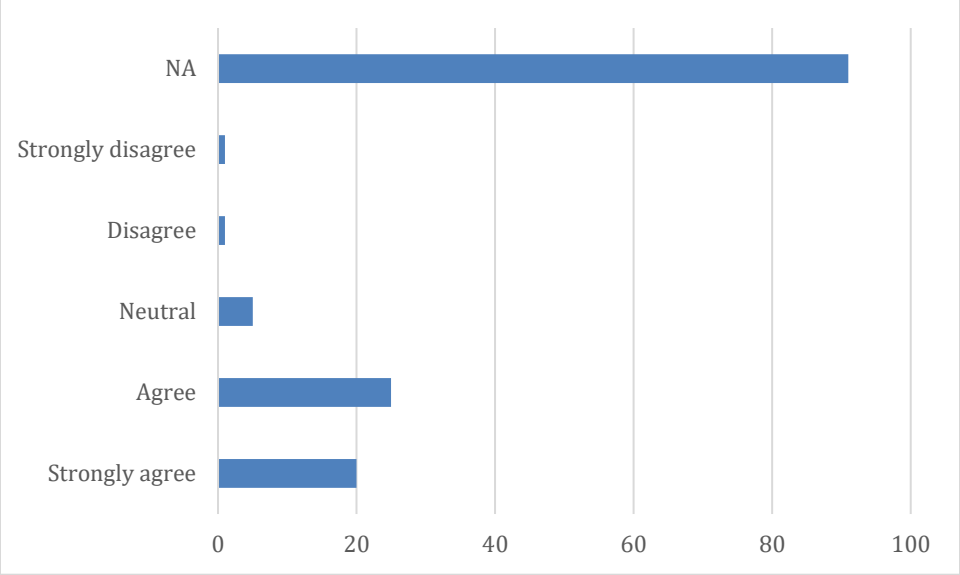

Figure 33: Collaboration between pharmaceutical companies and medical device manufacturers essential for this technology success

For the purpose of ensuring the successful development of Wireless Capsule Endoscopy (WCE) with medication administration, the information presented in Table 28 reflects the opinions of respondents about the significance of cooperation between pharmaceutical firms and medical equipment makers. A total of 31.5% of participants, including 14.0% who strongly agree and 17.5% who agree, are of the opinion that such cooperation is necessary. On the other hand, 3.5% of participants maintain a neutral stance, while a very tiny number of participants disagree (0.7%) or strongly disagree (0.7%). In this particular setting, the majority of respondents (63.6% of them) answered NA (not applicable), which indicates that they have minimal understanding or expertise about multidisciplinary cooperation. Overall, the findings indicate that while a portion of the respondents acknowledge the significant role that cooperation plays, the majority of them are unable to make a conclusive evaluation as to its significance.

Q29. Do you consider regulatory pathways for combination products the main barrier to market entry?

Table 29: Regulatory pathways for combination products the main barrier to market entry

Answer	Frequency	Percent
Strongly agree	16	11.2
Agree	22	15.4
Neutral	13	9.1
Strongly disagree	1	.7
NA	91	63.6
Total	143	100.0

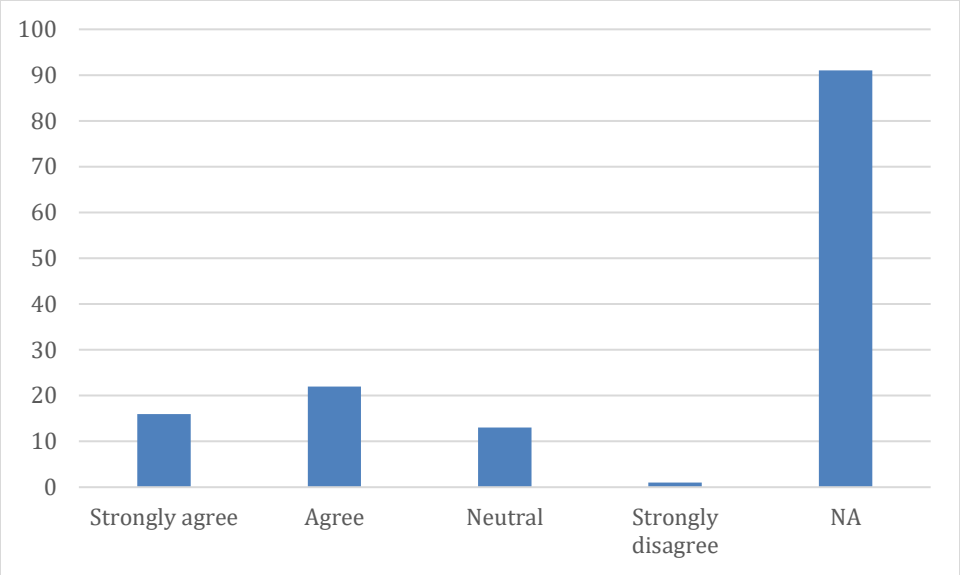

Figure 34: Regulatory pathways for combination products the main barrier to market entry

The perspectives of the respondents about the regulatory procedures necessary for combination goods as a barrier to market entrance are shown in Table 29. A total of 26.6% of participants, with 11.2% strongly agreeing and 15.4% agreeing, see regulatory requirements as a significant barrier. On the other hand, 9.1% of participants maintain a neutral stance, and 0.7% of people strongly disagree. 63.6 % of respondents said "no," which indicates that they have minimal understanding or expertise with the regulatory procedures for combination drug-device products. Based on these findings, it seems that some of the respondents acknowledge that regulatory issues are a serious worry; nonetheless, the majority of them are unable to make an educated evaluation.

Q30. How would you rate the commercial market potential for Wireless Capsule Endoscopy (WCE) -integrated drug delivery in gastrointestinal care?

Table 30: Commercial market potential of WCE-integrated drug delivery in gastrointestinal care

Answer	Frequency	Percent
Very high	6	4.2
High	21	14.7
Moderate	24	16.8
Very low	1	.7
NA	91	63.6
Total	143	100.0

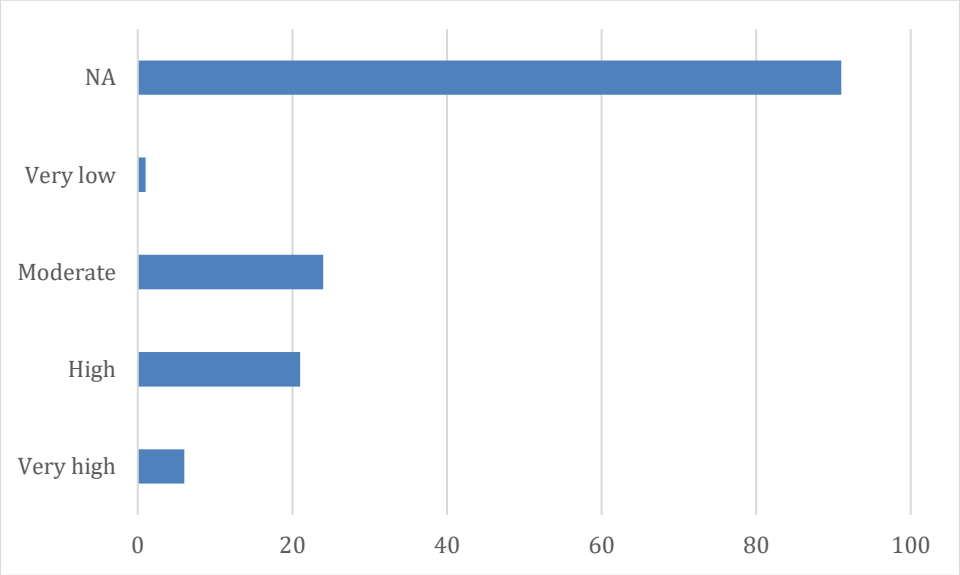

Figure 35: Commercial market potential of wireless capsule endoscopy-integrated drug delivery in gastrointestinal care

The opinions of those who participated in the survey are shown in Table 30, which deals with the commercial market potential of WCE with integrated medication administration in regards to gastrointestinal treatment. Among the participants, a total of 18.9% had a strong perception of the

market's potential, with 4.2% having a very high perception and 14.7% having a high perception. In contrast, 16.8% have a moderate perception, and 0.7% have a very low perception. NA (not applicable) was picked by the majority of respondents (63.6%), which indicates that there is little expertise or experience in evaluating the economic feasibility of this technology. Taking the whole into consideration, the findings indicate that while there are experts who see attractive market prospects, the majority of respondents are unable to make a decisive opinion.

4.3 Chapter summary

The demographic and professional profiles of the respondents, as well as their thoughts on the incorporation of medication administration into Wireless Capsule Endoscopy (WCE), were analysed in this chapter. The results showed that while a subgroup of professionals indicated optimism about the feasibility, therapeutic utility, and economic potential of this technology, the majority of respondents picked not applicable across a number of areas, which suggests that they had minimal understanding or competence in this specialized subject. Among the most significant issues that were observed were the inability to maintain medication stability in a variety of gastrointestinal settings, restrictions imposed by battery and power, and the intricacy of regulatory pathways. At the same time, possibilities were identified in the form of possible enhancements to patient care, a decreased dependence on invasive procedures, and the significance of multidisciplinary cooperation for the creation of successful products.

Chapter 5: Discussion

5.1 Introduction

This chapter discusses the study's findings and how they relate to the goals of the investigation as well as the corpus of existing research on Wireless Capsule Endoscopy (WCE) and its application to drug delivery systems. In order to provide a deeper understanding of the findings' significance, this chapter will provide an interpretation of the findings that were presented in the previous chapter as frequency distributions and descriptive statistics. The conversation is organized around the primary research goals and covers important topics like the technical viability of integrating drug delivery, pharmacological and clinical considerations, commercial and regulatory obstacles, and the anticipated adoption opportunities in gastrointestinal care. To determine whether the results complement, add to, or diminish the information currently available, the results are compared with those of previous research and industry reports. The findings' implications for pharmaceutical companies, makers of medical devices, healthcare providers, and regulatory agencies are also examined in this chapter. It highlights the potential of this new technology while also acknowledging the obstacles that must be removed in order to achieve successful clinical adoption. This is accomplished by assessing the practical implications of the findings.

5.2 Summary of the findings

i. The research indicates that the Wireless Capsule Endoscope (WCE) technology has made great progress beyond its initial diagnostic function. This advancement includes the incorporation of drug delivery methods, wireless telemetry, miniaturized sensors, and real-time imaging capabilities. The significant potential of this compound for diagnostic and therapeutic uses in gastrointestinal (GI) care is highlighted by recent developments in capsule design and pharmacokinetic measurement.

ii. Regarding the use and developmental features of WCE, respondents, on the whole, expressed good impressions. Clinical practitioners saw it as a tool that was both patient-friendly and less intrusive, while biomedical and pharmaceutical engineers stressed its potential to improve targeted medication release, customized treatment, and precision diagnostics. For broad clinical acceptance, however, there were issues expressed about the cost, uniformity, and scalability of the treatment.

iii. The findings identified a number of obstacles that interfere with the implementation of WCE. Among the technical concerns are the navigation of capsules, the stability of drugs inside the gastrointestinal system, and the guaranteeing of reliable data transfer. Validating pharmacokinetics and establishing consistent treatment results are two of the clinical challenges that might prove to be challenging. Complex clearance procedures, fragmented rules, and lengthy timescales are some of the regulatory impediments that have arisen as a key issue. Combination products are difficult to enter the market because of these requirements.

iv. Participants brought up significant possibilities despite the difficulties they faced. A non-invasive diagnostic, site-specific medication administration, less patient pain, and improved treatment compliance are all among the benefits that may be gained via WCE. Expanding its function in preventative medicine, the technology also has the potential to be integrated with artificial intelligence and machine learning for predictive analytics. One of the most important factors in optimizing the commercial and clinical potential of WCE was the collaboration between pharmaceutical firms, device makers, and regulatory agencies.

5.3 Discussion of findings with objectives

The purpose of this research was to evaluate the feasibility of incorporating drug-delivery systems into Wireless Capsule Endoscopy (WCE), as well as attitudes, challenges, and possible possibilities associated with this integration procedure. In light of previous research on developments in biomedical engineering, capsule-based diagnostics, and therapeutic applications, the results are reviewed in this context. On the other hand, the comparison between the findings of the survey with the research that have been published draws similarities between the adoption rates in India and Ireland, highlighting both the consistency and the gaps in the present body of information.

In terms of the practicality of integrating medicine delivery into WCE, the majority of respondents were either neutral or unsure, as evidenced by the survey findings (23.8% of respondents were neutral and 56.6% of respondents were not knowledgeable). This cautious perspective is consistent with the continued technical constraints that have been identified in several pieces of

research. Regarding the PillCam SB3, for example, Eliakim et al. (2010) and Franco et al. (2017) define it as a revolutionary diagnostic tool for the small intestine; nevertheless, they also point out that its capabilities are essentially diagnostic rather than therapeutic. It has also been confirmed by Baltes et al. (2018) and Deding et al. (2020) that devices like PillCam Crohn's and PillCam COLON 2 have better vision, but they do not have integrated therapeutic activities of their own. On the other hand, technical reviews (Chen et al., 2022; Sharova et al., 2021) highlight the fast innovation that is occurring in endurance, locomotion, localization, and communication. This is causing WCE to transition from a passive imaging equipment to an intelligent therapeutic platform. Despite the fact that technical advancement is well-documented, the professional community continues to have little understanding and trust in clinical feasibility, as shown by the neutral or doubtful posture taken by our respondents.

The survey results revealed that doctors and engineers exhibited a modest level of optimism with regards to miniaturization, actuator technologies, and biocompatibility, with around thirty percent of them agreeing with the statement. For example, IntroMedic's Miro (Kim et al., 2007), Jinshan's omom (Friedrich et al., 2013), and Ankon's Navicam (Liao et al., 2016) are examples of previous research that demonstrated advancements in micro-actuators, Micro-Electro-Mechanical-System (MEMS) imaging, and smart capsules. The acknowledgment of miniaturization advances by our respondents is reflected in the fact that these gadgets demonstrate the increasing complexity of capsule technologies.

The issues that were mentioned in our findings about the limits of the battery (30.1% of respondents agreed or strongly agreed) are similar to the constraints that Chen et al. (2022) noted. Traditional batteries made of silver oxide have a limited durability, whilst solutions made of lithium-ion polymer raise concerns about safety. A practical understanding that while theoretical solutions such as wireless power transfer (Sharova et al., 2021) and edible electronics are available, they have not yet been extensively incorporated into clinical-grade capsules is reflected in the skepticism of the respondents.

According to the results of the poll, the most significant hurdles are seen to be the cost, the cost of the battery, and the regulatory requirements. The obstacles that have been mentioned in the literature are strengthened by our results. For example, there are still problems with localization and communication that have not been resolved: While Zeising et al. (2022) emphasize the limits

of magnetic and video-based localization, Li et al. (2021) reveal that there are bandwidth restrictions in radio-frequency transmission when it comes to signal transmission.

In terms of clinical applications, our respondents expressed confusion about the validation of pharmacokinetics (25.9% of them were neutral) and drug stability in the gastrointestinal tract (25.2% of them were in agreement or strongly agreed). These limitations are in line with the concerns that were brought up by Qiu et al. (2019), who pointed out the difficulty of assuring accurate and on-demand medication release in an environment that is dynamic in the gastrointestinal tract.

Regarding the regulatory front, a sizeable proportion of respondents came to the conclusion that combination product rules would need substantial redesigns (35.7% of respondents agreed or strongly agreed. Comparative policy evaluations are consistent with this finding: in India, fragmented Central Drug Standard Control Organization (CDSCO) approvals cause translation to be delayed (CDSCO, 2021; Patel & Desai, 2023), while Ireland reaps the advantages of simplified EU Medical Device Regulation procedures (HPRA, 2020; Ross et al., 2020). Therefore, our results are consistent with the previous research, highlighting the importance of regulation as a significant barrier.

The poll revealed that there is optimism over the improvement of patient outcomes and acceptability, notwithstanding the limitations posed by technological and regulatory issues. As an example, respondents concurred that WCE had the potential to lessen the number of recurrent invasive operations (16.1% of respondents agreed or strongly agreed), and that patient acceptability would be high (14.7% of respondents agreed or strongly agreed). The results presented here are in agreement with those of Rahim et al. (2020), who revealed that AI-assisted WCE achieved diagnosis accuracy of more than 95%, hence minimizing the need for invasive endoscopies. In addition, respondents highly supported the idea of cooperation between pharmaceutical corporations and device makers (21.5 percent of respondents agreed or strongly agreed with this statement). This is similar to the continuing collaborations between business and academics in Ireland (Lamprou et al., 2023; Cortegoso Valdivia et al., 2021) and the burgeoning low-cost WCE projects in India (Tiwari et al., 2012; Elumalai et al., 2024). Because of the confluence of these relationships, the potential of WCE as a multifunctional platform for diagnosis and tailored treatment has been highlighted.

Chapter 6: Conclusion and recommendations

6.1 Research conclusion

The purpose of this study was to investigate the developments, perceptions, and other obstacles that are related with Wireless Capsule Endoscopy (WCE), with a particular emphasis on its diagnostic capabilities as well as its possible integration with medication delivery systems. The results of this study demonstrate that WCE has seen substantial development over the course of the last twenty years, notably with the advent of high-resolution imaging, longer battery life, enhanced navigation systems, and the possibility of tailored therapeutic treatments. Considering these improvements, it is clear that WCE is becoming an increasingly important minimally invasive technique in the field of gastrointestinal treatment. Furthermore, the research demonstrated that medical experts, physicians, biomedical engineers, and pharmaceutical professionals generally see WCE as a very promising technology. This is particularly true with regard to the enhancement of diagnostic accuracy, the improvement of patient comfort, and the facilitation of site-specific medication release. On the other hand, respondents also emphasized the importance of further technical development, particularly with regard to the stability of medication formulations, capsule control, and real-time monitoring via integrated sensors.

Despite the fact that it holds promises, the implementation of WCE confronts significant obstacles. Not all of the technical obstacles that have been encountered, such as capsule retention, restricted power supply, and difficulty in guaranteeing medication stability in a variety of gastrointestinal situations, have been overcome. Continuing to be difficult in the clinical setting, quantifying pharmacokinetics and verifying results in large-scale studies are both challenging. Regulatory frameworks have been cited as a key impediment for market entrance on several occasions. This is due to the complex categorization of WCE as a drug-device combination product. These limitations, when taken together, slow down the rate at which clinical acceptance and commercialization are occurring. The study on the other hand, highlights significant prospects and promise for the future. Providing targeted medication administration, decreasing systemic side effects, and allowing real-time biomarker identification for precision medicine are all ways in which WCE has the potential to change healthcare for the gastrointestinal tract. With the help of shortened regulatory processes and collaboration between pharmaceutical firms and producers of medical devices, this transformation will be a significant step forward. In the field of

gastrointestinal care, the economic potential of WCE is acknowledged, provided that research and development efforts continue to fill in the gaps that that now present.

6.2 Strategic conclusion

The outcomes of this study underline the fact that WCE, when combined with medication delivery and modern imaging technologies, is strategically positioned to change the healthcare that is provided to the gastrointestinal tract. Because of its dual diagnostic and therapeutic qualities, it presents a one-of-a-kind potential for a paradigm shift away from traditional invasive treatments and toward alternatives that are minimally invasive and focused on the patient. However, in order to fully achieve this potential, it is necessary to take concerted strategic action across the technological, clinical, regulatory, and commercial sectors concerned. Continuing to invest in the design of capsules, the efficiency of batteries, navigational control, and the incorporation of biosensors is crucial from a technical point of view. The diagnostic accuracy will be improved as a result of these improvements, and they will also make it possible to precisely release drugs in specific parts of the gastrointestinal tract. For the purpose of addressing issues related to formulation stability and device-drug compatibility, strategic cooperation between biomedical engineers and pharmaceutical scientists will be imperative. The clinical front requires a priority to be placed on large-scale studies and clinical validations that take place in the real world in order to generate confidence and acceptance among medical professionals. Clinicians need to be strategically involved in the co-development process in order to guarantee usability, safety, and workflow integration, which will ultimately lead to a wider adoption of WCE in clinical settings. Regulatory frameworks that are simplified and standardized for combination goods are strategically significant. This is because of the regulatory viewpoint. Commercialization is considerably hampered by the regulatory uncertainties that are now in place; hence, proactive contact with regulatory bodies is required. As a result of clearer paths, clearance timeframes will be accelerated, uncertainties will be reduced, and industry investment will be encouraged. Demonstrating cost-effectiveness, patient compliance, and lower long-term treatment costs in comparison to traditional treatments are the three most important factors that determine the economic feasibility of WCE in terms of market strategy. Maximizing acceptance, scaling manufacturing, and constructing a business environment that is sustainable will need the formation

of strategic partnerships between pharmaceutical firms, makers of medical devices, and healthcare providers.

6.3 Recommendations

Following are some suggestions that have been suggested in light of the results of this research in order to strategically advance the development, adoption, and commercialization of WCE:

i. The importance of making investments in research and development of diagnostic functions of the wireless capsule endoscope along with target drug delivery capacities. By this we can enhance the capsule navigation, power efficiency and biosensor integration.
ii. Encouraging the cooperation of biomedical engineers with pharmaceutical researchers can solve challenges in medication stability, dose management and capsule compatibility with the design.
iii. Large scale clinical studies must be encouraged to confirm efficacy, safety and reliability of the integrated Wireless Capsule Endoscope (WCE) in health care setting.
iv. The end-users and the physicians must be participating in the design and testing phases to ensure the usability and a smooth integration into preexisting process in healthcare industry.
v. Creating awareness by conducting educational programs for medical professionals and technicians to help them become more self-assured its usage.
vi. The early interaction with the regulatory bodies ensures minimization of delays in approval and eliminate uncertainty in product development.
vii. The establishment of defined procedures and compliance criteria is necessary in order to guarantee safety, effectiveness, and widespread acceptance.
viii. Encourage the formation of public-private partnerships between healthcare providers, device makers, and pharmaceutical companies in order to speed up the process of entering the market.

6.4. Future Research and Development

i. Advance research on capsule-based multi-therapy applications, including simultaneous imaging, biopsy, and medication release, among other potential uses.

ii. As a means of tailoring communication and increasing adoption rates, it is important to investigate patient views and acceptability.

iii. It is important to investigate the possibility of integrating digital health platforms for the purposes of telemedicine and remote monitoring.

REFERENCE LIST

Adler, S.N., 2017. The history of time for capsule endoscopy. *Annals of Translational Medicine*, 5(9), p.194. doi:10.21037/atm.2017.03.90.

Ali, M.A. *et al.* (2025) 'Recent Advancements in Localization Technologies for Wireless Capsule Endoscopy: A Technical Review', *Sensors*, 25(1), pp. 253–253. Available at: https://doi.org/10.3390/s25010253.

Ali, M.A., Tom, N., Alsunaydih, F.N. and Yuce, M.R., 2025. Recent Advancements in Localization Technologies for Wireless Capsule Endoscopy: A Technical Review. *Sensors (Basel, Switzerland), 25*(1), p.253.https://doi.org/10.3390/s25010253

Al-Jaber, H., Biswas, K.H. and Al-Mansoori, L., (2025). Advancing targeted therapy for colorectal cancer: harnessing ligand-directed enzyme prodrug therapy for highly specific interventions. *Frontiers in Oncology*, *15*, p.1570712. https://doi.org/10.3389/fonc.2025.1570712

Baltes, P., Bota, M., Albert, J., Philipper, M., Hörster, H.-G., Hagenmüller, F., Steinbrück, I., Jakobs, R., Bechtler, M., Hartmann, D., *et al.*, 2018. PillCamColon2 after incomplete colonoscopy—A prospective multicenter study. *World Journal of Gastroenterology*, 24, pp.3556–3564.

Banerjee, A., Qi, J., Gogoi, R., Wong, J. and Mitragotri, S. (2016) 'Role of nanoparticle size, shape and surface chemistry in oral drug delivery', *Journal of Controlled Release*, 238, pp. 176–185. doi:10.1016/j.jconrel.2016.07.051.

Bianchini, E. and Mayer, C.C., (2022). Medical device regulation: should we care about it?. *Artery Research*, *28*(2), pp.55-60. https://link.springer.com/content/pdf/10.1007/s44200-022-00014-0.pdf

Boegh, M. and Nielsen, H.M. (2015) 'Mucus as a barrier to drug delivery - understanding and mimicking the barrier properties', *European Journal of Pharmaceutics and Biopharmaceutics*, 96, pp. 437–447. doi:10.1016/j.ejpb.2015.08.004.

Cao, Q. *et al.* (2024) 'Robotic wireless capsule endoscopy: recent advances and upcoming technologies', *Nature Communications*, 15(1). Available at: https://doi.org/10.1038/s41467-024-49019-0.

Cao, Q., Deng, R., Pan, Y., Liu, R., Chen, Y., Gong, G., Zou, J., Yang, H. and Han, D., (2024). Robotic wireless capsule endoscopy: recent advances and upcoming technologies. *Nature Communications*, *15*(1), p.4597. https://doi.org/10.1038/s41467-024-49019-0

Carpi, F., Galbiati, S. and Carpi, A., 2007. Controlled navigation of endoscopic capsules: Concept and preliminary experimental investigations. *IEEE Transactions on Biomedical Engineering*, 54(11), pp.2028–2036. https://doi.org/10.1109/TBME.2007.895740

Central Drugs Standard Control Organization (CDSCO), 2021. *Guidelines for medical devices*. New Delhi: CDSCO.

Chang-Chao, S., Chou, C.-K., Mukundan, A., Karmakar, R., Sanbatcha, B.F., Huang, C.-W., Weng, W.-C. & Wang, H.-C., 2025. Capsule endoscopy: Current trends, technological advancements, and future perspectives in gastrointestinal diagnostics. *Bioengineering*, 12(6), p.613.

Chen, K. *et al.* (2022) 'An edible and nutritive zinc-ion micro-supercapacitor in the stomach with ultrahigh energy density', *ACS Nano*, 16, pp. 15261–15272. doi:10.1021/acsnano.2c06656.

Chu, J.N. and Traverso, G., 2022. Foundations of gastrointestinal-based drug delivery and future developments. *Nature Reviews Gastroenterology & Hepatology*, *19*(4), pp.219-238. https://doi.org/10.1038/s41575-021-00539-w

Connor, A., Evans, P., Doto, J., Ellis, C. and Martin, D.E., 2009. An oral human drug absorption study to assess the impact of site of delivery on the bioavailability of bevirimat. *European Radiology*, 19(5), pp.1224–1230. https://doi.org/10.1007/s00330-008-1281-6

Cortegoso Valdivia, P., Robertson, A.R., De Boer, N.K.H., Marlicz, W. and Koulaouzidis, A., 2021. An overview of robotic capsules for drug delivery to the gastrointestinal tract. *Journal of Clinical Medicine*, 10(24), p.5791. https://doi.org/10.3390/jcm10245791

Crater, J.S. and Carrier, R.L. (2010) 'Barrier properties of gastrointestinal mucus to nanoparticle transport', *Macromolecular Bioscience*, 10(12), pp. 1473–1483. doi:10.1002/mabi.201000112.

Deding, U., Kaalby, L., Bøggild, H., Plantener, E., Wollesen, M.K., Kobaek-Larsen, M., Hansen, S.J. & Baatrup, G., 2020. Colon capsule endoscopy vs. CT colonography following incomplete colonoscopy: A systematic review with meta-analysis. *Cancers*, 12, p.3367.

Deepak Bajhaiya and Sujatha Narayanan Unni (2024) 'Deep learning-enabled detection and localization of gastrointestinal diseases using wireless-capsule endoscopic images', *Biomedical signal processing and control (Print)*, 93, pp. 106125–106125. Available at: https://doi.org/10.1016/j.bspc.2024.106125.

Eliakim, R., Sharma, V.K., Yassin, K. *et al.*, 2006. A prospective study of the diagnostic accuracy of PillCam ESO esophageal capsule endoscopy versus conventional upper endoscopy in patients with chronic gastroesophageal reflux diseases. *Gastroenterology*, 131(2), pp.527–537. https://doi.org/10.1053/j.gastro.2006.05.052

Eliakim, R., Yassin, K., Niv, Y., Metzger, Y., Lachter, J., Ga, E., Sapoznikov, B., Konikoff, F., Leichtmann, G., Fireman, Z., *et al.*, 2010. Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. *Endoscopy*, 23, pp.144–149.

Elumalai, K., Srinivasan, S. and Shanmugam, A., 2024. Review of the efficacy of nanoparticle-based drug delivery systems for cancer treatment. *Biomedical Technology*, 5, pp.109–122. https://doi.org/10.1016/j.bmt.2023.09.001

Fossum, E.R., 1997. CMOS image sensors: electronic camera-on-a-chip. *IEEE Transactions on Electron Devices*, 44(10), pp.1689–1698.

Franco, D.L., Leighton, J.A. & Gurudu, S.R., 2017. Approach to incomplete colonoscopy: New techniques and technologies. *Gastroenterology & Hepatology*, 13, p.476.

Friedrich, K., Gehrke, S., Stremmel, W. & Sieg, A., 2013. First clinical trial of a newly developed capsule endoscope with panoramic side view for small bowel: A pilot study. *Journal of Gastroenterology and Hepatology*, 28, pp.1496–1501.

Gagliardi, J., (2024). *Share of adults diagnosed with gastrointestinal conditions in the United Kingdom in 2018, by age**. Statista. Available at: https://www.statista.com/statistics/420260/gastrointestinal-conditions-by-gender-and-age-in-the-united-kingdom/

George, A.A., Tan, J.L., Kovoor, J.G., Lee, A., Stretton, B., Gupta, A.K., Bacchi, S., George, B. and Singh, R., (2024). Artificial intelligence in capsule endoscopy: development status and future expectations. *Mini-invasive Surgery*, *8*, pp.N-A.https://doi.org/10.20517/2574-1225.2023.102

Ghanad, A., (2023). 'An overview of quantitative research methods'. *International journal of multidisciplinary research and analysis*, 6(08), pp.3794-3803. Available at: https://doi.org/10.47191/ijmra/v6-i8-52

Habes, M., Ali, S. and Pasha, S.A., (2021). 'Statistical package for social sciences acceptance in quantitative research: from the technology acceptance model's perspective'. *FWU Journal of Social Sciences*, 15(4), pp.34-46. Available at: https://ojs.sbbwu.edu.pk/fwu-journal/index.php/ojss/article/download/837/12#page=37

Hanscom, M. and Cave, D.R., (2022). Endoscopic capsule robot-based diagnosis, navigation and localization in the gastrointestinal tract. *Frontiers in Robotics and AI*, *9*, p.896028. https://doi.org/10.3389/frobt.2022.896028

Hany, U., Nafe Muhtasim Hye and Akter, L. (2023) 'Path Loss Based Wireless Capsule Endoscope Localization Using Machine Learning Regression', *IEEE access*, 11, pp. 124643–124659. Available at: https://doi.org/10.1109/access.2023.3329812.

Hasan, A.M., Cavalu, S., Kira, A.Y., Hamad, R.S., Abdel-Reheim, M.A., Elmorsy, E.A., El-Kott, A.F., Morsy, K., AlSheri, A.S., Negm, S. and Saber, S., 2025. Localized drug delivery in different gastrointestinal cancers: navigating challenges and advancing nanotechnological solutions. *International Journal of Nanomedicine*, pp.741-770.https://doi.org/10.2147/IJN.S502833

Health Products Regulatory Authority (HPRA), 2020. *Medical device regulatory framework*. Dublin: HPRA.

Hossan, D., Dato'Mansor, Z. and Jaharuddin, N.S., (2023). 'Research population and sampling in quantitative study'. *International Journal of Business and Technopreneurship (IJBT)*, 13(3), pp.209-222. Available at: https://www.researchgate.net/profile/Dalowar-Hossan/publication/375127568_Research_Population_and_Sampling_in_Quantitative_Study/links/65490f9cb1398a779d693d9d/Research-Population-and-Sampling-in-Quantitative-Study.pdf

Iddan, G., Meron, G., Glukhovsky, A. & Swain, P., 2000. Wireless capsule endoscopy. *Nature*, 405(6785), p.417.

Indian Council of Medical Research (ICMR), 2017. *National ethical guidelines for biomedical research*. New Delhi: ICMR.

International Medical Device Regulators Forum (IMDRF) (2023) *International Medical Device Regulators Forum Report*.

Ionescu, A. *et al.* (2022) 'Clinical impact of wireless capsule endoscopy for small bowel investigation (Review)', *Experimental and Therapeutic Medicine*, 23(4). Available at: https://doi.org/10.3892/etm.2022.11188.

Ismail, Y. and Kishore, S., 2025. Recent advances in targeted drug delivery systems: Review article. *Journal of Pharma Insights and Research*, 3(2), pp.031–042. https://doi.org/10.69613/q3mj7z06

Jain, S. *et al.* (2021) 'A deep CNN model for anomaly detection and localization in wireless capsule endoscopy images', *Computers in Biology and Medicine*, 137, p. 104789. Available at: https://doi.org/10.1016/j.compbiomed.2021.104789.

Kagan, L. and Hoffman, A. (2008) 'Systems for region selective drug delivery in the gastrointestinal tract: biopharmaceutical considerations', *Expert Opinion on Drug Delivery*, 5(6), pp. 681–692. doi:10.1517/17425247.5.6.681.

Kim, J. *et al.* (2022) 'Redundant electromagnetic control of an endoscopic magnetic capsule driven by multiple electromagnets configuration', *IEEE Transactions on Industrial Electronics*, 69, pp. 11370–11382. doi:10.1109/TIE.2021.3120443.

Kim, T.S., Song, S.Y., Jung, H., Kim, J. & Yoon, E.-S., 2007. Micro capsule endoscope for gastrointestinal tract. In *Proceedings of the 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, Lyon, France, 22–26 August 2007. IEEE, New York, NY, USA.

Kotla, N.G., Rana, S., Sivaraman, G. *et al.*, 2019. Bioresponsive drug delivery systems in intestinal inflammation: State-of-the-art and future perspectives. *Advanced Drug Delivery Reviews*, 146, pp.248–266. https://doi.org/10.1016/j.addr.2018.06.021

Kotronoulas, G., Miguel, S., Dowling, M., Fernández-Ortega, P., Colomer-Lahiguera, S., Bağçivan, G., Pape, E., Drury, A., Semple, C., Dieperink, K.B. and Papadopoulou, C., (2023), April. 'An overview of the fundamentals of data management, analysis, and interpretation in quantitative research'. In *Seminars in oncology nursing* (Vol. 39, No. 2, p. 151398). WB Saunders. Available at: https://doi.org/10.1016/j.soncn.2023.151398

Lamprou, D. and Ryan, K.B., 2023. Drug formulation and delivery: a UK and Ireland perspective. *Drug Delivery and Translational Research*, 13, p.2057. https://doi.org/10.1007/s13346-023-01358-z

Laroui, H., Dalmasso, G., Nguyen, H.T.T., Yan, Y., Sitaraman, S.V. and Merlin, D. (2011) 'Drug-loaded nanoparticles targeted to the colon with polysaccharide hydrogel reduce colitis in a mouse model', *Gastroenterology*, 138(3), pp. 843–853. doi:10.1053/j.gastro.2009.11.003.

Leenhardt, R., Dray, X. & Histace, A., 2021. Clinical context for wireless capsule endoscopy image analysis. In *Computer-Aided Analysis of Gastrointestinal Videos*, pp.9–13.

Li, R. and Guo, Y. (2021) 'A conformal UWB dual-polarized antenna for wireless capsule endoscope systems', *IEEE Antennas and Wireless Propagation Letters*, 20, pp. 483–487. doi:10.1109/LAWP.2021.3054676.

Liao, Z., Hou, X., Lin-Hu, E.-Q., Sheng, J.-Q., Ge, Z.-Z., Jiang, B., Hou, X.-H., Liu, J.-Y., Li, Z., Huang, Q.-Y. *et al.* (2016) 'Accuracy of magnetically controlled capsule endoscopy, compared with conventional gastroscopy, in detection of gastric diseases', *Clinical Gastroenterology and Hepatology*, 14, pp. 1266–1273.e1.

Liu, W., Choi, S.J., George, D., Li, L., Zhong, Z., Zhang, R., Choi, S.Y., Selaru, F.M. and Gracias, D.H., (2023). Untethered shape-changing devices in the gastrointestinal tract. *Expert opinion on drug delivery, 20*(12), pp.1801-1822.https://doi.org/10.1080/17425247.2023.2291450

Maretha, C., (2023). 'Positivism in philosophical studies'. *Journal of Innovation in Teaching and Instructional Media*, 3(3), pp.124-138. Available at: https://pdfs.semanticscholar.org/9e89/639ea6052cf6fe7714717090868f0f2542c9.pdf

Medtronic (2021) *PillCam™ SB3 CE Mark Documentation*. Dublin, Ireland: Medtronic.

Mehedi, I.M. *et al.* (2023) 'Intelligent Wireless Capsule Endoscopy for the Diagnosis of Gastrointestinal Diseases', *Diagnostics*, 13(8), pp. 1445–1445. Available at: https://doi.org/10.3390/diagnostics13081445.

Mellinger, C.D. and Hanson, T.A., (2020). Methodological considerations for survey research: Validity, reliability, and quantitative analysis. Linguistica Antverpiensia, New Series–Themes in Translation Studies, 19. https://doi.org/10.52034/lanstts.v19i0.549

Miftahof, R.N., 2005. *Biomechanics of the human stomach*. Springer Science & Business Media.

Muñoz, F., Alici, G. and Li, W. (2019) 'A review of drug delivery systems for capsule endoscopy', *Advanced Drug Delivery Reviews*, 71, pp. 77–85. doi:10.1016/j.addr.2013.09.001.

Muruganantham, P. and Balakrishnan, S.M. (2021) 'A survey on deep learning models for wireless capsule endoscopy image analysis', *International Journal of Cognitive Computing in Engineering*, 2, pp. 83–92. Available at: https://doi.org/10.1016/j.ijcce.2021.04.002.

Naser, M., Naser, M.M. and Shehata, L.H. (2016) 'Wireless Capsule Endoscopy (WCE): Review', *International Journal of Progressive Sciences and Technologies*, 36(1), pp. 150–167. Available at: https://doi.org/10.52155/ijpsat.v36.1.4845.

Olympus Medical Systems Corp., 2005. *EndoCapsule system technical specifications* [Technical report]. Olympus Corporation.

Paynter, C., McDonald, C., Story, D. and Francis, J.J., (2023). 'Application of the theoretical framework of acceptability in a surgical setting: theoretical and methodological insights'. *British Journal of Health Psychology*, 28(4), pp.1153-1168. Available at: DOI: 10.1111/bjhp.12677

Pennazio, M.J.D. (2006) 'Capsule endoscopy: Where are we after 6 years of clinical use?', *Digestive and Liver Disease,* 38, pp. 867–878.

Qin, K. *et al.* (2021) 'Convolution neural network for the diagnosis of wireless capsule endoscopy: a systematic review and meta-analysis', *Surgical Endoscopy*, 36(1), pp. 16–31. Available at: https://doi.org/10.1007/s00464-021-08689-3.

Qiu, Y. *et al.* (2020) 'Ultrasound capsule endoscopy with a mechanically scanning micro-ultrasound: A porcine study', *Ultrasound in Medicine & Biology*, 46, pp. 796–804. doi:10.1016/j.ultrasmedbio.2019.12.003.

Rahim, T., Usman, M.A. and Shin, S.Y. (2020) 'A survey on contemporary computer-aided tumor, polyp, and ulcer detection methods in wireless capsule endoscopy imaging', *Computerized Medical Imaging and Graphics*, 85, p. 101767. doi:10.1016/j.compmedimag.2020.101767.

Ramoni, D., Scuricini, A., Carbone, F., Liberale, L. and Montecucco, F., (2025). Artificial intelligence in gastroenterology: Ethical and diagnostic challenges in clinical practice. *World Journal of Gastroenterology*, *31*(10), p.102725. https://doi.org/10.3748/wjg.v31.i10.102725

Rey, J.F., *et al.*, 2004. Video capsule endoscopy in gastroenterology. *Endoscopy*, 36(1), pp.1–12.

Ross, A.M., Kennedy, T., McNulty, D., Leahy, C.I., Walsh, D.R., Murray, P., Grabrucker, A.M. and Mulvihill, J.J.E., 2020. Comparing nanoparticles for drug delivery: The effect of physiological dispersion media on nanoparticle properties. *Materials Science and Engineering: C*, 113.

Shah, A. *et al*. (2023) 'Miniaturized Four-Port MIMO Implantable Antenna for High-Data-Rate Wireless-Capsule-Endoscopy Applications', *IEEE Transactions on Antennas and Propagation*, 71(4), pp. 3123–3133. Available at: https://doi.org/10.1109/tap.2023.3243984.

Sharova, A.S., Melloni, F., Lanzani, G., Bettinger, C.J. and Caironi, M. (2021) 'Edible electronics: The vision and the challenge', *Advanced Materials Technologies*, 6, p. 2000757. doi:10.1002/admt.202000757.

Sivasubramaniam, S., Dlabolová, D.H., Kralikova, V. and Khan, Z.R., (2021). 'Assisting you to advance with ethics in research: an introduction to ethical governance and application procedures'. *International Journal for Educational Integrity*, 17(1), p.14. Available at: https://doi.org/10.1007/s40979-021-00078-6

Steiger, C., Abramson, A., Nadeau, P. *et al.* (2021) 'Ingestible electronics for diagnostics and therapy', *Nature Reviews Materials*, 6(2), pp. 127–148. doi:10.1038/s41578-020-00270-z.

Subramanian, D.A., Langer, R. and Traverso, G. (2022) 'Mucus interaction to improve gastrointestinal retention and pharmacokinetics of orally administered nano-drug delivery systems', *Journal of Nanobiotechnology*, 20(1), p. 362.

Swain, P., Gong, F., Mills, T. & Shing, J., 2001. Wireless capsule endoscopy of the small bowel: development, testing and first human trial. *Nature Medicine*, 7(12), pp.1–5.

Swan, M.P., Bourke, M.J., Moss, A., Williams, S.J., Hopper, A. and Metz, A., 2009. The target lesion detection rate of small-bowel capsule endoscopy. *Gut*, 58(3), pp.361–366. https://doi.org/10.1136/gut.2008.150680

Taherdoost, H., (2021). 'Data collection methods and tools for research; a step-by-step guide to choose data collection technique for academic and business research projects'. *International*

Journal of Academic Research in Management (IJARM), 10(1), pp.10-38. Available at: https://hal.science/Hal-03741847/

Taherdoost, H., (2022). What are different research approaches? Comprehensive review of qualitative, quantitative, and mixed method research, their applications, types, and limitations. *Journal of Management Science & Engineering Research*, *5*(1), pp.53-63. https://doi.org/10.30564/jmser.v5i1.4538

Tekade, R.K., Maheshwari, R., Soni, N., Tekade, M. & Chougule, M.B., 2017. Nanotechnology for the development of nanomedicine. In *Nanotechnology-Based Approaches for Targeting and Delivery of Drugs and Genes*. Elsevier, pp.3–61. doi:10.1016/B978-0-12-809717-5.00001-4.

Thomson, M., (2021). Wireless capsule endoscopy. *Practical Pediatric Gastrointestinal Endoscopy*, pp.129-139. https://doi.org/10.1002/9781119423492.ch15

Tiwari, G., Tiwari, R., Sriwastawa, B., Bhati, L., Pandey, S., Pandey, P. and Bannerjee, S.K., 2012. Drug delivery systems: An updated review. *International Journal of Pharmaceutical Investigation*, 2(1), pp.2–11. https://doi.org/10.4103/2230-973X.96920

Trivedi, D., Thummar, K., Maheriya, B. and Chauhan, S., (2025). Navigating the Regulatory Landscape: Key Transformations in India's Drug & Clinical Trials Regulations-A Comparative Analysis with the USA & Europe.*Advances in Pharmacology and Pharmacy 13*(2), 204-213. DOI: 10.13189/app.2025.130205

Wang, A., Banerjee, S., Barth, B.A., Bhat, Y.M., Chauhan, S., Gottlieb, K.T., Konda, V., Maple, J.T., Murad, F. and Pfau, P.R. (2013) 'Wireless capsule endoscopy', *Gastrointestinal Endoscopy*, 78, pp. 805–815.

Wang, G. *et al.* (2025) 'A Review on the Current Research Status of Key Areas in Wireless Capsule Endoscopy', *International Journal of Medical Robotics and Computer Assisted Surgery*, 21(4). Available at: https://doi.org/10.1002/rcs.70094.

Wang, W., Yan, X., Li, Q., Chen, Z., Wang, Z. and Hu, H. (2020) 'Adapted nano-carriers for gastrointestinal defense components: surface strategies and challenges', *Nanomedicine*, 29, p. 102277.

Wang, X., Hu, X., Xu, Y., Yong, J., Li, X., Zhang, K., Gan, T., Yang, J. and Rao, N., (2023). A systematic review on diagnosis and treatment of gastrointestinal diseases by magnetically controlled capsule endoscopy and artificial intelligence. *Therapeutic Advances in Gastroenterology*, *16*, p.17562848231206991. https://doi.org/10.1177/17562848231206991

Wang, X., Meng, M.Q.-H. and Hu, C., 2006. A localization method using 3-axis magnetoresistive sensors for tracking of capsule endoscope. *IEEE Sensors Journal*, 6(3), pp.689–696. https://doi.org/10.1109/JSEN.2006.874499

William, F.K.A., (2024). 'Mastering validity and reliability in academic research: Meaning and significance'. *International Journal of Research Publications*, 144(1), pp.287-292. Available at: https://www.researchgate.net/profile/Arthur-William-Fodouop-Kouam/publication/378770310_Mastering_Validity_and_Reliability_in_Academic_Research_Meaning_and_Significance/links/65e8fc03adf2362b637d0879/Mastering-Validity-and-Reliability-in-Academic-Research-Meaning-and-Significance.pdf

Woods, S.P. and Constandinou, T.G., 2012. Wireless capsule endoscope for targeted drug delivery: Mechanics, design and implementation considerations. *IEEE Transactions on Biomedical Engineering*, 59(4), pp.945–953. https://doi.org/10.1109/TBME.2011.2182193

Xiao, Z. *et al.* (2022) 'WCE-DCGAN: A data augmentation method based on wireless capsule endoscopy images for gastrointestinal disease detection', *IET image processing*, 17(4), pp. 1170–1180. Available at: https://doi.org/10.1049/ipr2.12704.

Yu, M.K., Park, J. and Jon, S. (2012) 'Targeting strategies for multifunctional nanoparticles in cancer imaging and therapy', *Theranostics*, 2(1), pp. 3–44. doi:10.7150/thno.3463.

Zeising, S., Thalmayer, A.S., Lübke, M., Fischer, G. and Kirchner, J. (2022) 'Localization of passively guided capsule endoscopes—A review', *IEEE Sensors Journal*, 22, pp. 20138–20155. doi:10.1109/JSEN.2022.3205721.

Zhang, X., Xu, X., Chen, Y., Dou, Y., Zhou, X., Li, L., Li, C., An, H., Tao, H., Hu, H., Li, X. and Zhang, J. (2017) 'Bioinspired yeast microcapsules loaded with self-assembled nanotherapies for targeted treatment of cardiovascular disease', *Materials Today*, Elsevier.

Zheng, G., Zhang, B., Yu, H., Song, Z., Xu, X., Zheng, Z., Zhao, K., Zhao, J. and Zhao, Y., (2025). Therapeutic applications and potential biological barriers of nano-delivery systems in common gastrointestinal disorders: a comprehensive review. *Advanced Composites and Hybrid Materials, 8*(2), pp.1-22.https://doi.org/10.3390/pr9091527

Zwinger, L.L., Siegmund, B., Stroux, A., Adler, A., Veltzke-Schlieker, W., Wentrup, R., Jürgensen, C., Wiedenmann, B., Wiedbrauck, F., Hollerbach, S. *et al.* (2019) 'CapsoCam SV-1 versus PillCam SB 3 in the detection of obscure gastrointestinal bleeding: Results of a prospective randomized comparative multicenter study', *Journal of Clinical Gastroenterology*, 53, pp. e101–e106.

APPENDIX A – ETHICS DECLARATION FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: *Exploring Expert Perspectives on the Integration of Targeted Drug Delivery Mechanisms with Wireless Capsule Endoscopy: A Qualitative Study on Opportunities and Barriers in Advancing Precision Gastrointestinal Therapies*

RESEARCHER'S NAME: Dr. Neehara Bijal Kumaraswamy

PROGRAMME OF STUDY: MSc in Medical Device Technology & Business

SUPERVISOR'S NAME: Dr. Javed Iqbal

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:

DATE:7/07/2025

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

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

SUPERVISOR SIGNATURE:

DATE:07/07/2025

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

The purpose of this research is to comprehensively explore the integration of targeted drug delivery mechanisms with wireless capsule endoscopy (WCE) technology, aiming to advance precision therapies in gastrointestinal (GI) care. Wireless capsule endoscopy has revolutionized GI diagnostics by enabling minimally invasive visualization of the entire gastrointestinal tract. However, coupling this diagnostic capability with targeted therapeutic delivery presents a promising frontier that could significantly enhance treatment efficacy, reduce systemic side effects, and improve patient outcomes. This study seeks to bridge the gap between emerging technological innovations and clinical application by examining expert perspectives on this integration.

The objectives of the research are fourfold:

1. To systematically review and analyse recent advancements in wireless capsule endoscopy and targeted drug delivery systems, focusing on their current and potential applications in gastrointestinal healthcare.
2. To gather and synthesize expert opinions from pharmaceutical researchers, biomedical engineers—particularly those affiliated with industry leaders such as Medtronic and Olympus—and clinicians. This will provide insights into the technical feasibility, clinical usability, and practical considerations of developing drug delivery-enabled capsule endoscopes.
3. To identify and investigate the key barriers and challenges hindering the adoption and implementation of integrated capsule endoscopy devices. These include technical limitations, regulatory hurdles, and clinical acceptance issues.
4. To assess future opportunities and the potential benefits of adopting targeted drug delivery integrated with wireless capsule endoscopy, highlighting how this innovation could transform precision GI therapies and patient care paradigms.

1.2 Research methodology:

A total sample size of approximately **150 participants** is targeted to ensure sufficient representation across the three expert groups. The survey will consist of structured, closed-ended questions with Likert scales and multiple-choice items, as well as a limited number of open-ended questions to allow elaboration on key points. The questionnaire will be divided into sections addressing recent technological advancements, clinical feasibility, regulatory and technical barriers, and future opportunities.

Collected data will be analyzed using descriptive and inferential statistics, including frequency distributions, cross-tabulations, and chi-square tests to identify significant patterns and relationships among variables. Qualitative responses will be subjected to thematic analysis to supplement quantitative findings with contextual insights. Findings will be presented through comprehensive reports featuring charts, tables, and narrative summaries, providing a clear and objective assessment of expert opinions to inform future development and clinical adoption of drug delivery integrated capsule endoscopy.

SECTION 2: POSSIBLE ETHICAL ISSUES

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

SUBJECT MATTER

Does the research proposal involve:

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

RESEARCH PROCEDURES

Does the research proposal involve:

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

PARTICIPANTS

Does the research proposal involve:

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

(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

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.

My study include gastroenterologist as one of the subjects and since they are commonly in a hospital setup the ethical consideration arises, but these professionals maybe contacted only through emails and social links with the referencing from people who already now them. The research follows a snowball method of sample collection. And no personal data from the professionals are collected such as age, name and address, only the years of experience in the field of gastroenterology is assessed

3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.

The ethics does not relate with the 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.

No ethics needed in relation to participants. The personal data is not collected.

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].*

- **Pharmaceutical researchers** specializing in drug delivery systems, who provide insights on formulation, targeting mechanisms, and regulatory considerations.

- **Biomedical engineers**, particularly those affiliated with leading medical technology companies such as Medtronic and Olympus, who contribute expertise in device design, integration, and technical feasibility.
- **Clinicians**, including gastroenterologists and other specialists experienced in gastrointestinal diagnostics and therapy, who offer perspectives on clinical usability, patient care implications, and adoption barriers.

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

- Initial contacts will be made via professional networks, industry partnerships, and academic collaborators known to the research team.
- Invitations to participate will be disseminated through targeted emails, LinkedIn groups, and relevant professional forums to reach pharmaceutical researchers, biomedical engineers, and clinicians.
- Snowball sampling will encourage participants to refer colleagues with relevant expertise, expanding the pool organically.
- Recruitment communications will include clear information about the study's purpose, confidentiality assurances, and voluntary participation to encourage engagement.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

PIL will be provided in Appendix 2

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

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

No: my research study involves an online survey only and/or does not require signed consent. Consent will be included in the online survey as follows:

1.Do you consent to participate in this study?

- Yes, I consent to participate.
- No, I do not consent to participate

SECTION 6: STORAGE OF DATA

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

All research data collected from the online surveys, including raw responses and analysis files, will be stored securely on a password-protected electronic device,

primarily in the laptop. To prevent data loss, a backup copy will be maintained on a secure cloud storage platform such as OneDrive, which offers encryption and controlled access.

The data will be retained for a period of **up to two years** following the completion of the research and award of the qualification. This retention period complies with relevant data protection regulations and allows for any necessary further analysis, verification, or academic review. After this period, all data will be permanently and securely deleted.

Data Protection Measures:

1. **Anonymization:** Any personally identifiable information (e.g., names, email addresses) will be removed or replaced with unique participant codes to ensure anonymity and confidentiality. Survey responses will be stored in anonymized form to prevent identification of individual participants or their organizations.
2. **Password Protection:** All electronic files containing research data will be secured with strong, unique passwords, accessible only by the principal researcher.
3. **Restricted Access:** Access to the data will be limited to the research team. For thesis submission and academic purposes, anonymized datasets will be uploaded securely to the institution's submission platform (e.g., Moodle).
4. **Encryption:** Both the laptop and cloud storage services will utilize encryption protocols to safeguard data against unauthorized access or breaches.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

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

No

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

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

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

SECTION 9: DOCUMENT CHECKLIST

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

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

9.1 Participant Information Letter (PIL) for participant	Yes
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
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: 

DATE: 07/07/2025

APPENDIX A – SURVEY QUESTIONS

consent form,

Hi everyone,

My name is Neehara Bijal Kumaraswamy, a postgraduate student in the MSc in Medical Device Technology and Business program at Griffith College, Dublin. I am conducting this research as part of my Master's degree.

The purpose of this study is to explore expert perspectives on the integration of targeted drug delivery systems with wireless capsule endoscopy (WCE), and to identify the opportunities and barriers in advancing precision gastrointestinal therapies. Your insights as a Biomedical Engineer, Gastroenterologist, or Pharmaceutical Researcher are vital to the success of this research.

Participation in this study is entirely voluntary. You have the right to decline or withdraw from the survey at any time before submitting your responses, without facing any negative consequences.

If you agree to participate, you will be asked to complete a short online survey, which should take approximately 5 minutes. Please read each question carefully and answer based on your professional knowledge and experience.

please note,

If you are selecting **Biomedical Engineer** please fill **only Section A.**

If you are selecting **Gastroenterologist** please fill **only Section B.**

If you are selecting **Pharmaceutical Researcher** please fill **only Section C.**

Your responses will be kept anonymous and confidential. No personally identifiable information such as your name, email address, or IP address will be collected. The survey will include questions about your professional views on the feasibility, benefits, and challenges of integrating drug delivery mechanisms into WCE technologies. Some questions may ask about your field of specialization or experience level to contextualize responses, but these will not be linked to your identity.

All collected data will be used solely for academic research purposes and securely stored in compliance with GDPR and institutional ethical research guidelines.

By proceeding to the next page, you confirm that you have read and understood the information above, and you voluntarily agree to participate in this study.

Thank you very much for your time and valuable contribution.

Do you consent to participate in this study ?

- ○ Yes, I consent to participate
- ○ No, I do not consent to participate

ter section 1 Go to section 2 (GENERAL QUESTIONS- please answer)

Section 2 of 5

GENERAL QUESTIONS- please answer

Every person taking the survey must answer these 3 questions 2,3,4.

Are you currently practicing or working in any of these positions Ireland or India?

- ○ Biomedical Engineer
- ○ Gastroenterologist
- ○ Pharmaceutical Researcher

Which location are you currently practicing ? *

- ○ India
- ○ Ireland

How many years of professional experience do you have ?

- ○ 0 - 5 years
- ○ More than 5 years

SECTION A – BIOMEDICAL ENGINEER

1. Do you think recent advancements in WCE hardware make it technically feasible to integrate a drug-delivery mechanism?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
2. In your view, is current miniaturisation and micro-actuator technology sufficient for reliable drug release inside a capsule?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
3. Do you consider battery life and power limitations as the biggest technical challenge to adding drug delivery to WCE?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
4. Can current WCE sensing and communication technologies support real-time location tracking and targeted drug release?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
5. Do you believe adding drug reservoirs will significantly increase the manufacturing cost of WCE devices?

6. Are current biomedical engineering practices adequate to ensure biocompatibility and safe materials for an integrated capsule?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
7. Are current engineering collaborations with pharmaceutical partners sufficient to design a combined drug-device product?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
8. Do you think regulatory requirements for combination products will require major design changes early in development?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
9. How likely is your organisation to develop an integrated WCE + drug delivery prototype within the next 3 years?
    - Very unlikely
    - Unlikely
    - Neutral
    - Likely
    - Very likely

SECTION B GASTROENTEROLOGIST

5. How familiar are you with targeted drug delivery systems for gastrointestinal applications?

- Not familiar
- Slightly familiar
- Moderately familiar
- Very familiar
- Extremely familiar

5. Would a WCE with targeted drug delivery improve patient outcomes for conditions such as IBD and small bowel disease?

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

6. Could WCE-based drug delivery reduce the need for repeated invasive endoscopies or systemic treatments?

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

7. Do you think patient acceptance would be high for a drug-delivering capsule compared to pills or injections?

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

8. Would concerns about capsule retention or device-related complications limit adoption in clinical practice?

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

9. For which condition would drug-delivering WCE be most clinically useful?

- Localised inflammatory lesions (e.g., Crohn's)

- Tumour-directed therapy (small bowel)
- Local infection / antimicrobial delivery
- Post-surgical site therapy
- Other (please specify) _____

10. Would the ability to diagnose and deliver drugs simultaneously in one procedure streamline patient care?

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

11. How extensive do you think the training requirements would be for gastroenterologists to use WCE-based drug delivery?

- Minimal
- Slight
- Moderate
- Significant
- Extensive

12. Do you consider reimbursement and patient cost a major barrier to adoption?

- Yes
- No
- Not sure

13. If proven safe and effective, how likely would you be to adopt WCE with targeted drug delivery within 5 years?

- Very unlikely
- Unlikely
- Neutral
- Likely
- Very likely

SECTION C – PHARMACEUTICAL RESEARCHER

1. Do you believe delivering drugs via WCE could improve local therapeutic efficacy compared to systemic dosing?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
2. Can current pharmaceutical technologies formulate drugs that are stable and effective for capsule-mediated delivery?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
3. Is ensuring drug stability in varying gastric and intestinal pH levels a major challenge for WCE drug delivery?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
4. Would integrating sensors into WCE to detect local environment (e.g., pH, biomarkers) be useful for precise drug release?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
5. Do you think manufacturing and quality-control processes for combined drug-device products will be more complex than device-only or drug-only products?
    - 1- Strongly disagree
    - 2- Disagree
    - 3- Neutral
    - 4- Agree
    - 5- Strongly agree
6. Can clinical pharmacokinetics of drug release from capsules be reliably measured and validated in trials?
    - 1- Strongly disagree

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

7. Is collaboration between pharmaceutical companies and medical device manufacturers essential for this technology's success?

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

8. Do you consider regulatory pathways for combination products the main barrier to market entry?

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

9. How would you rate the commercial market potential for WCE-integrated drug delivery in gastrointestinal care?

   - Very low
   - Low
   - Moderate
   - High
   - Very high

APPENDIX B – PATIENT INFORMATION LETTER

PARTICIPANT INFORMATION LETTER

TITLE OF THE STUDY: Exploring Expert Perspectives on the Integration of Targeted Drug Delivery Mechanisms with Wireless Capsule Endoscopy: A Qualitative Study on Opportunities and Barriers in Advancing Precision Gastrointestinal Therapies

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 Neehara Bijal Kumaraswamy, pursuing an MSc in Medical Device Technology and Business at Griffith College, Dublin. I am conducting this research to gather expert perspective about integrating Target Drug Delivery method into the existing Wireless Capsule Endoscopy and to further asses the challenges and opportunities of such an integration.

WHAT WOULD TAKING PART INVOLVE?

Taking part in this study, "Exploring Expert Perspectives on the Integration of Targeted Drug Delivery Mechanisms with Wireless Capsule Endoscopy," involves sharing your professional insights through interviews or surveys focused on the opportunities and challenges of combining these technologies for precision gastrointestinal therapies. Your contributions will help identify key factors affecting the development and adoption of such innovations, including technical, clinical, and regulatory aspects. All information you provide will be kept strictly confidential and anonymous, ensuring that no individual participant can be identified in any reports or publications. By participating, you will play a valuable role in advancing academic knowledge and supporting the future improvement and implementation of targeted drug delivery integrated with wireless capsule endoscopy.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in this research because you are an expert with relevant knowledge or experience in the field of targeted drug delivery and wireless capsule endoscopy technologies. Your insights are essential for understanding the opportunities and barriers involved in integrating these advanced drug delivery mechanisms with wireless capsule endoscopy to advance precision gastrointestinal therapies. By sharing your professional perspective, you will help identify key factors influencing the development, clinical adoption,

and future potential of these innovative therapies, contributing valuable information to guide research and implementation in this emerging area.

DO YOU HAVE TO TAKE PART?

Participation in this study is entirely voluntary and you have the right to refuse or withdraw at any point before submitting your answers, without incurring any penalties or negative consequences.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Participating in this study involves minimal risk, as it primarily consists of confidential interviews or surveys where no personal or sensitive information will be collected. Some participants might feel slight discomfort when discussing professional challenges or opinions related to targeted drug delivery and wireless capsule endoscopy technologies, but you are free to skip any questions or withdraw at any time. While there are no direct personal benefits, your participation will provide valuable insights into the opportunities and barriers in integrating these advanced therapies, which could help shape future research, development, and clinical practices in precision gastrointestinal treatments.

WILL TAKING PART BE CONFIDENTIAL?

Yes, your participation in this study will be entirely confidential and anonymous. The survey does not gather any personal information including your name, email address, or IP address. All responses will be kept safe and utilized solely for Academic purpose.
Since the research is survey based and will not involve interviews or recordings, there will be no collection of signed consent forms or personal audio information. Thereby assuring that confidentiality is never broken in this study.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All research information including gathered survey responses and documents related to analysis/findings will be stored securely in a password-protected Google Drive account in an electronic device(laptop). Data will be kept securely, and it is utilized exclusively for academic purposes in line with institutional regulations and kept in accordance with GDPR and Ethical research standards.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The findings from this study will be used solely for the completion of a master's dissertation within an MSc in Medical Device Technology and Business program at Griffith College Dublin. A copy of the completed dissertation will be provided to the college and made available in the Griffith College library. It might also be part of the college's digital repository or electronic journals, if applicable.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?
Name: Neehara Bijal Kumaraswamy
Contact: +353 894324878
Email ID: neeharabijal.kumaraswamy.@student.griffith.ie