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# Opportunities and Challenges in Implementing Digital Health Technologies in Decentralised Clinical Trials: A Comparative Analysis of India and Ireland

A dissertation submitted in partial fulfilment of the requirements for MSc in Pharmaceutical Business and Technology


**By**

**GIFTY PETER**

Innopharma Faculty of Pharmaceutical Science

**Griffith College, Dublin**


**MAY 2024**

# DECLARATION

I declare that the work done in this dissertation titled "Opportunities and Challenges in Implementing Digital Health Technologies in Decentralised Clinical Trials: A Comparative Analysis of India and Ireland" which I am currently submitting for evaluation as a requirement for my Masters in "Pharmaceutical Business and Technology," is entirely original work of my own. I have cited the work of others, and also proper acknowledgment has been provided.

**Candidate Signature:**

**Supervisor Name: Dr. Munira Derby**

**Date: 12/05/2025**

# ACKNOWLEDGMENT

First and foremost, I give thanks to God Almighty for the strength, wisdom, and guidance throughout this research journey.

My deepest gratitude goes to my supervisor, Dr. Munira Derby, for her invaluable expertise, patience, and unwavering support. Her insightful feedback and encouragement were instrumental in shaping this work.

To my parents, whose sacrifices, love, and prayers have been my foundation—thank you for your endless belief in me. My heartfelt appreciation also extends to my friends for their motivation and companionship during this challenging yet rewarding process.

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Lastly, I extend my sincere thanks to Innopharma Education and the lecturers and staff at Griffith College for sharing their knowledge, experiences, and support throughout my academic journey. This accomplishment is a testament to their dedication and inspiration.

# ABSTRACT

## Opportunities and Challenges in Implementing Digital Health Technologies in Decentralized Clinical Trials: A Comparative Analysis of India and Ireland

***Gifty Peter***

This study explored the adoption, opportunities, and challenges of Digital Health Technologies (DHTs) in Decentralized Clinical Trials (DCTs) across India and Ireland. Using a mixed-methods approach, quantitative data were collected through surveys of clinical research professionals (n=133), and qualitative insights were gathered from five semi-structured interviews. The research revealed that Ireland demonstrated higher levels of DHT adoption, with more organizations reporting advanced or fully integrated systems, compared to India's early-stage adoption and infrastructural limitations. Telemedicine platforms, remote monitoring devices, and mobile health apps were among the most widely used tools in both countries, although usage varied significantly. The COVID-19 pandemic acted as a key accelerator for DHT implementation in both the country. Real-time data collection, improved patient engagement, and reduced burden of site visits were identified as key benefits. However, significant challenges persist. In India, these included poor internet connectivity, digital illiteracy, and usability barriers, whereas Ireland's primary challenges related to workforce training and data governance. Patients across both regions generally responded positively to DHTs, with younger participants showing greater comfort. Contract Research Organizations (CROs) were found to play a critical role in facilitating DHT integration, particularly in training, platform selection, and data management. The study concludes that region-specific strategies are needed to optimize DHT adoption—addressing infrastructure and training in India and enhancing interoperability and regulatory clarity in Ireland. Recommendations include investing in digital infrastructure, strengthening CRO partnerships, co-designing user-friendly platforms, and implementing public awareness campaigns. This research contributes comparative insights into DHT implementation in two regulatory environments and offers actionable guidance for stakeholders aiming to enhance the reach and efficiency of decentralized trials.

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| | |
|---|---|
| AI | Artificial Intelligence |
| CAGR | Compound Annual Growth Rate |
| CDSCO | Central Drugs Standard Control Organization (India) |
| CRO | Contract Research Organization |
| CTR | Clinical Trials Regulation (EU) |
| DCT | Decentralized Clinical Trial |
| DCGI | Drugs Controller General of India |
| DHT | Digital Health Technology |
| DPDP | Digital Personal Data Protection Act (India) |
| EC | Ethics Committee |
| EDC | Electronic Data Capture |
| EHR | Electronic Health Record |
| EHDS | European Health Data Space |
| EMA | European Medicines Agency |
| eCOA | Electronic Clinical Outcome Assessment |
| FDA | Food and Drug Administration (USA) |
| GCP | Good Clinical Practice |
| HIPAA | Health Insurance Portability and Accountability Act (USA) |
| HSE | Health Service Executive (Ireland) |
| HTA | Health Technology Assessment |
| ICF | Informed Consent Form |
| ICMR | Indian Council of Medical Research |
| IRB | Institutional Review Board |
| MDR | Medical Device Regulation (EU) |
| NDHM | National Digital Health Mission (India) |
| OECD | Organisation for Economic Co-operation and Development |
| PMCF | Dep. of Pharmaceuticals Ministry Of Chemicals & Fertilizers Government Of India |
| PRO | Patient-Reported Outcome |
| R&D | Research and Development |

| | |
|---|---|
| RWD | Real-World Data |
| SPDI | Sensitive Personal Data or Information (India) |
| USD | United States Dollar |
| VR/AR | Virtual Reality / Augmented Reality |
| WHO | World Health Organization |

# 1 INTRODUCTION

## 1.1 BACKGROUND AND CONTEXT

Clinical trials are essential in the drug development process, playing a critical role in evaluating the safety and efficacy of new treatments before they reach the market. These trials contribute to the advancement of therapeutic interventions, vaccines, and medical devices, ultimately improving healthcare outcomes (Mishra, 2022). However, traditional clinical trials have long faced challenges such as high operational costs, slow patient recruitment, logistical burdens, and participant retention issues (Kim et al., 2023; de Jong et al.,2022)

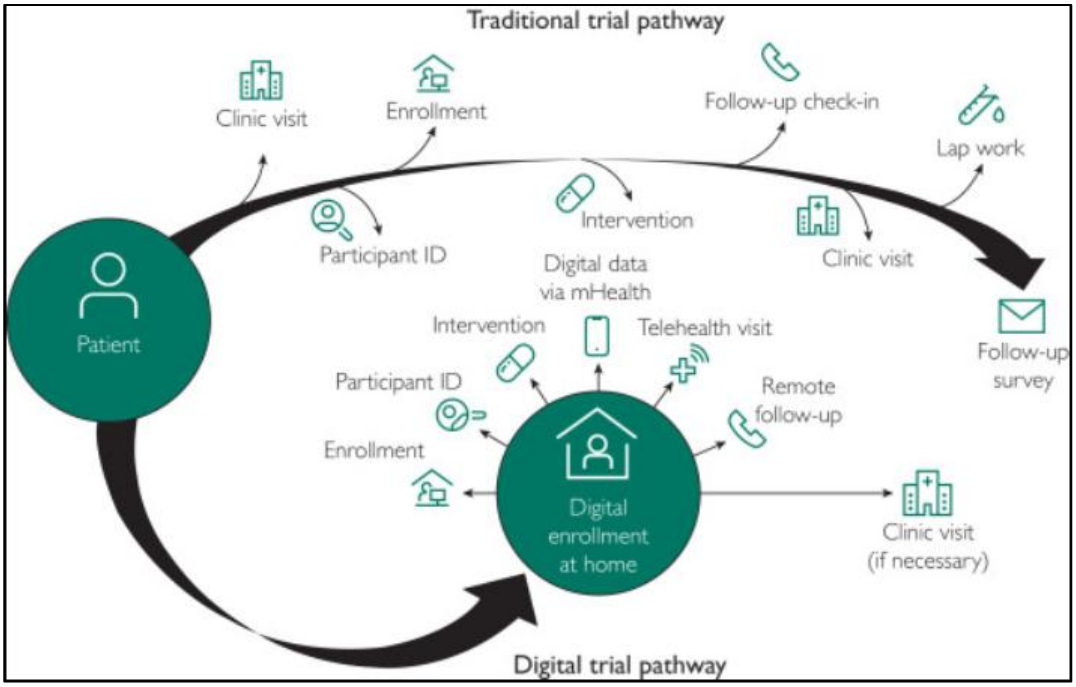



*Figure 1.1-1 Decentralized Clinical trials(Harmon* et al*., 2023)*

Over the past decade, there has been a significant increase in the use of digital health technologies—tools that operate through mobile devices and the Internet—to support healthcare delivery on a global scale (Bhavnani *et al.*, 2016; Trifan *et al.*, 2019; Agrawal and Prabakaran, 2020). Simultaneously, the widespread adoption of smartphones has led to people being constantly connected online, with social media platforms becoming a primary space for

communication, community interaction, and information sharing (Pew Research Center, 2019; Pew Research Center, 2024). This resulted in a significant transformation of the clinical trial landscape, leading to the adoption of Digital Health Technologies (DHTs) into clinical research.

In 2000, only eight clinical trials adopted DHTs in their trial setting, however, by 2017, the number had increased to 1,100 trials(Marra *et al.*, 2020) (Figure 1.1.2). It has been estimated that by 2025, 70% of clinical trials will incorporate digital tools(Jansen and Thronton, 2020). The COVID-19 pandemic was a major catalyst for this transformation, disrupting traditional trial operations due to lockdowns and social distancing measures, forcing sponsors to implement remote patient monitoring, eConsent, and telehealth solutions (FDA, 2024a; Van, 2021).

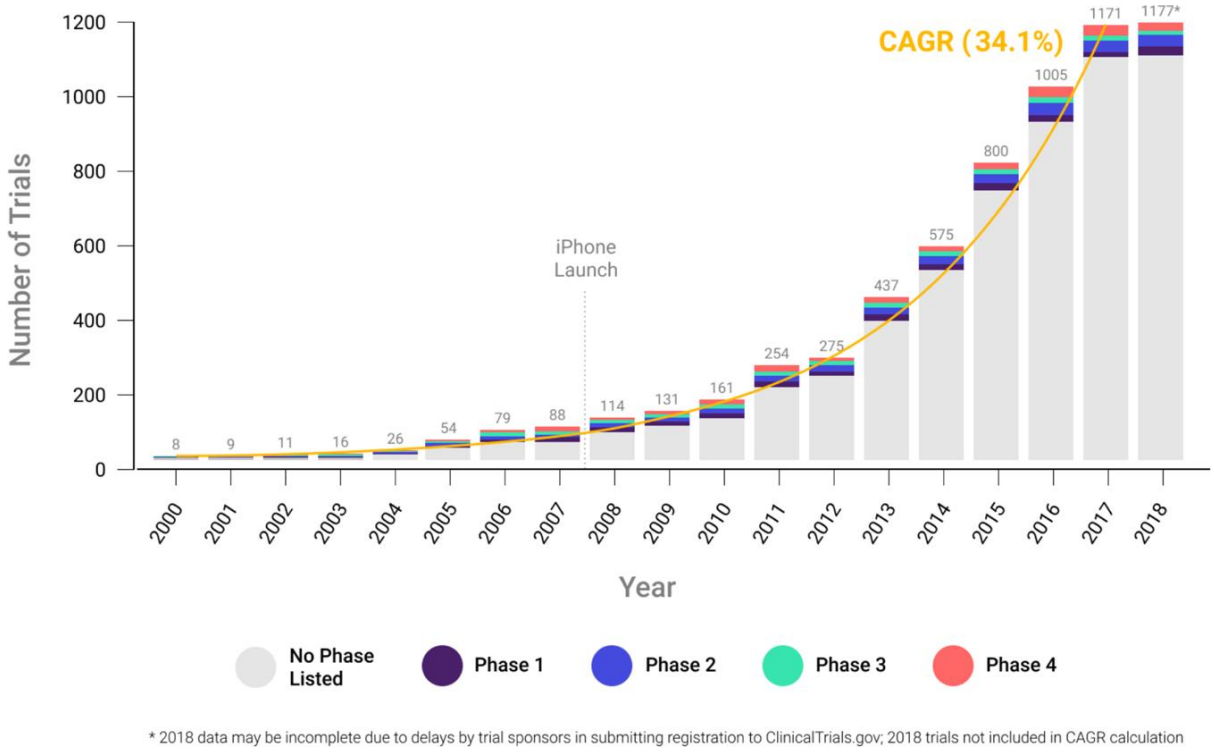



*Figure 1.1-2Clinical trials using connected digital products by study start year and phase.(Marra et al., 2020)*

DHTs, including telemedicine, wearable devices, electronic data capture systems, artificial intelligence (AI), and remote monitoring tools, have reshaped how trials are conducted (Mittermaier et al., 2023). These advancements have enabled the emergence of Decentralized Clinical Trials (DCTs), which shift away from traditional site-based models to more patient-

centric approaches (Copland et al., 2024). Unlike conventional trials, which require participants to visit hospitals or research centers for screenings, treatments, and follow-ups, DCTs leverage DHTs to allow participants to engage in clinical research from their homes or local healthcare facilities (Anthes, 2021; Duran and Bonam, 2023).

DCTs and DHTs have gained significant momentum due to technological advancements, increasing acceptance of telemedicine, and the need for more efficient and accessible clinical trial models. Regulatory agencies such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) introduced guidelines to support decentralized and hybrid trials, encouraging greater adoption of digital tools in clinical research (Dorsey et al., 2020). As a result, pharmaceutical companies and Contract Research Organizations (CROs) have increasingly embraced DHTs to enhance trial efficiency and accessibility (Vayena et al., 2023).

Traditional trials often exclude individuals who live in rural areas, have mobility limitations, or face socioeconomic barriers. DCTs may improve diversity in clinical research by reducing geographical and logistical obstacles, allowing individuals from underrepresented populations to participate remotely. This inclusivity is vital for generating more representative clinical data, ensuring that treatments are effective across different demographic and genetic backgrounds (FDA, 2024).

Despite numerous advantages, DHTs also introduce new challenges. Secure data management, compliance with regulatory frameworks, training for both participants and research staff, and digital literacy disparities are among the key barriers that need to be addressed. Additionally, access to technology remains a significant limitation, as some patients may lack smart devices, internet connectivity, or familiarity with digital tools. These concerns must be carefully managed to maximize the potential of DCTs while ensuring trial integrity and patient safety(de Jong *et al.*, 2022).

Pharmaceutical companies, CROs, are increasingly embracing DHTs to optimize trial efficiency and also many Institutional review Boards(IRBs) and regulatory agencies have released several guidance on the use of digital tools in clinical trials. ((Rosa *et al.*, 2021; FDA, 2024a; FDA, 2024b)). However, the implementation of DCTs varies significantly across countries due to differences in regulatory frameworks, digital infrastructure, and clinical research practices.

**Digital Health Landscape in Ireland and India**

Ireland, despite ranking as the EU's 5th most advanced digital economy (DESI), demonstrates surprisingly low digital health maturity, placing last among the developed nations in health system readiness. The Irish healthcare system continues to grapple with fragmented data governance, heavy reliance on paper-based records, and siloed health information (HSE, 2024; Sullivan, 2023). These systemic challenges have limited the adoption of digital therapeutics and remote monitoring solutions, contributing to Ireland's relatively low attractiveness for clinical trials compared to European peers (IPHA, 2024).

India presents a contrasting scenario, where policy initiatives like the National Digital Health Mission (NDHM) aim to create unified digital health ecosystems. However, implementation faces substantial hurdles including rural-urban disparities in technology access, variable digital literacy, and fragmented health infrastructure (APACMed, 2022). While telemedicine adoption has expanded significantly, particularly through private sector innovation, systemic barriers persist in creating equitable digital health access nationwide.

Both nations face distinct yet parallel challenges - Ireland struggles with integrating advanced digital solutions into a tech-capable system, while India must overcome fundamental infrastructure and accessibility gaps. Understanding these contextual differences is crucial for developing tailored approaches to DHT implementation in decentralized clinical trials, particularly in addressing data governance, stakeholder coordination, and equitable service delivery across diverse healthcare landscapes.

This comparative analysis provides critical insights into the adoption barriers, infrastructural, and sociotechnical factors influencing DHT adoption, informing strategies to enhance clinical trial methodologies while ensuring patient safety and health system efficiency in both developed and emerging digital health markets.

## 1.2 RESEARCH QUESTIONS

This study is guided by the following research questions:

1. What is the current level of adoption of Digital Health technologies in clinical trials, and what are the different types of DHTs available?

2. What are the key opportunities and benefits of implementing Digital Health Technologies (DHTs) in Decentralized Clinical Trials (DCTs) in India and Ireland?
3. How do digital tools impact patient recruitment, retention, and engagement in decentralized trials, and what are the variations between India and Ireland?
4. What are the major barriers and challenges affecting the adoption of DHTs in DCTs across these two countries?
5. What role do Contract Research Organizations (CROs), regulatory bodies, and other key stakeholders play in facilitating the adoption of DHTs in DCTs?
6. What strategies and best practices can enhance the successful integration and long-term sustainability of DHTs in decentralized clinical trials?

## 1.3 RESEARCH HYPOTHESIS

- **H1:** Covid-19 accelerated the adoption of Digital Health Technologies in Clinical trials
- **H2:** Digital health technologies improve patient recruitment, retention, and data quality in decentralized clinical trials.

## 1.4 AIM:

To examine the opportunities and challenges in implementing digital health technologies in decentralized clinical trials (DCTs) by comparing their adoption, regulatory landscape, and operational effectiveness in India and Ireland.

### 1.5 OBJECTIVES

The primary objectives of this study are:

**Objective I**: **To assess the current level of adoption and types of Digital Health Technologies (DHTs)—such as telemedicine, e-consent, remote monitoring, and wearable devices—used in decentralized clinical trials (DCTs) in India and Ireland.**

This objective assesses DHT adoption levels in clinical trials across India and Ireland, examining technologies like telehealth, e-consent, and wearables. The comparison reveals each region's digital maturity and integration in decentralized trials.

**Objective II: To evaluate the operational benefits and perceived impact of DHTs on key clinical trial outcomes, including patient recruitment, retention, data collection, and trial efficiency.**

This objective evaluates how DHTs enhance decentralized trials by improving recruitment, data accuracy, and participant adherence through real-world professional insights.

**Objective III: To identify and analyse the key challenges that hinder the adoption of DHTs in DCTs across both regions.**

Despite the growing interest in DHTs, various barriers still limit their widespread use. These include poor internet connectivity in remote areas, lack of participant or staff digital literacy, resistance to change, limited regulatory guidance, and concerns over data security. This objective aims to uncover these challenges from the perspective of professionals working in clinical research, helping to identify priority areas for policy improvement, training, and infrastructure development in both countries.

**Objective IV: To evaluate the role of Contract Research Organizations (CROs) in integrating DHTs into DCTs in India and Ireland.**

CROs play a crucial role in supporting sponsors by managing trial logistics, technology implementation, and regulatory compliance. This objective explores how CROs contribute to the adoption of DHTs in decentralized trials, including the extent of their involvement in technology selection, data management, and participant engagement. Understanding this role helps to clarify whether CROs act as facilitators or barriers to innovation, and how their expertise can be leveraged for better digital trial execution.

**Objective V: To identify emerging trends and future expectations for the adoption and expansion of DHTs in decentralized clinical research, based on stakeholder insights from both regions.**

This objective focuses on forward-looking perspectives to assess how the landscape of decentralized trials may evolve. By gathering insights on anticipated changes—such as

increased use of artificial intelligence, blockchain for data integrity, or mobile health applications—this analysis helps map future opportunities. It also aims to capture professionals' expectations regarding regulatory changes, industry investments, and the long-term sustainability of DHT adoption in India and Ireland.

**Objective VI: To provide actionable recommendations for CROs, sponsors, and regulators to optimize the use of DHTs in DCTs.**

Based on the findings from both quantitative and qualitative data, this objective translates insights into practical guidance. Recommendations will be tailored to address gaps in adoption, training, infrastructure, and regulatory alignment. These may include suggestions for capacity building, digital tool selection, policy harmonization, or stakeholder collaboration. The ultimate goal is to enable more effective, inclusive, and compliant use of DHTs in decentralized clinical research.

## 1.6 SIGNIFICANCE OF THE STUDY

The landscape of clinical trials is undergoing a paradigm shift with the growing integration of Digital Health Technologies (DHTs) into Decentralized Clinical Trials (DCTs). This transformation is reshaping how trials are designed, conducted, and managed—bringing research closer to the patient and reducing logistical and geographical barriers. Despite the promise of enhanced efficiency, accessibility, and patient-centricity, the adoption of DHTs in DCTs remains uneven across countries, particularly when comparing developed nations like Ireland to emerging economies like India.

This study holds significance as it explores the opportunities and challenges associated with implementing DHTs in DCTs, with a comparative focus on India and Ireland. These two countries represent contrasting healthcare infrastructures, digital maturity, and workforce readiness, making them ideal for understanding how these factors influence DCT adoption.

By engaging clinical trial professionals—including Clinical Research Associates, Clinical Trial Coordinators, Data Managers, and CRO professionals—through surveys and semi-structured interviews, the study captures frontline insights from those directly involved in trial operations

and digital tool deployment. This approach ensures a practical, operations-driven perspective on the effectiveness, feasibility, and barriers to implementing DHTs in real-world settings.

From a global health perspective, the successful integration of DHTs in DCTs can enhance trial inclusivity, improve data quality, and reduce trial timelines and costs. In India, DHTs could help overcome the urban-rural healthcare divide, while in Ireland, they offer the potential to streamline trials within an already digital-forward healthcare system. Insights from this study could support policy-makers, sponsors, Contract Research Organizations (CROs), and healthcare professionals in identifying actionable pathways for the effective deployment of DHTs(Rosa *et al.*, 2021).

The findings of this study can also inform future digital health policies, Implementation strategies, and best practices for trial decentralization. As the pharmaceutical industry and healthcare systems worldwide continue to embrace digital transformation, this research contributes timely and contextually relevant knowledge that bridges gaps between technology, regulation, and patient care.

## 1.7 STRUCTURE OF THE DISSERTATION

The study on Opportunities and Challenges in Implementing Digital Health Technologies in Decentralized Clinical Trials: A Comparative Analysis of India and Ireland follows a structured approach, outlined across multiple chapters.

### Chapter 1: Introduction

This chapter provides an overview of decentralized clinical trials (DCTs) and the role of digital health technologies (DHTs) in transforming the clinical research landscape in India and Ireland. It highlights the significance of the study, the research problem, and its objectives. Additionally, the research questions and the rationale behind this comparative analysis are presented.

### Chapter 2: Literature Review

This chapter explores existing research on DCTs and DHTs, focusing on their adoption, regulatory frameworks, infrastructure readiness, and operational challenges. Studies related to

patient recruitment, engagement, and data security in decentralized trials are examined. The literature review helps establish a theoretical framework for further research.

**Chapter 3: Research Methodology**

This chapter outlines the research design and methodology used to conduct the study. It details the research philosophy, approach, and strategy, as well as data collection methods, target population, and data analysis techniques. Ethical considerations and limitations of the study are also discussed.

**Chapter 4: Findings and Analysis**

The results of the study are presented and analysed based on the research objectives. A comparative analysis between India and Ireland is conducted to assess the adoption, regulatory challenges, and effectiveness of DHTs in decentralized trials. The findings are discussed in relation to existing literature to provide deeper insights.

**Chapter 5: Conclusion and Recommendations**

This chapter summarizes key findings and provides answers to the research questions. It discusses the implications of the study for stakeholders in clinical research, including regulators, sponsors, and healthcare providers. The limitations of the study and recommendations for future research and policy improvements are also outlined.

**References** – This lists all sources cited in the dissertation.

**Appendices** – Includes supplementary materials such as survey questionnaires and interview transcripts.

# 2 LITERATURE REVIEW

## 2.1 INTRODUCTION

The integration of Digital Health Technologies (DHTs) into Decentralized Clinical Trials (DCTs) marks a paradigm shift in clinical research, addressing longstanding challenges in traditional trials such as geographic barriers, high costs, and patient dropout rates (Dorsey *et al.*, 2020; Rosa *et al.*, 2021; Kim *et al.*, 2023). According to WHO, Digital Health is defined as " a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence" (WHO, 2019).

DHTs—including wearables, telemedicine, and e-consent platforms—enable remote participation, real-time data collection, and improved patient engagement (FDA, 2023). Unlike traditional site-based trials, DCTs are inherently patient-centric, allowing flexible participation tailored to diverse patient needs, thereby improving adherence and retention. Their scalability ensures that well-designed trials can efficiently expand to accommodate large patient populations, facilitating the collection of vast amounts of data. However, the global adoption of DHTs in DCTs varies significantly due to regulatory disparities, infrastructure limitations, and differing levels of stakeholder readiness (EMA, 2023; CDSCO, 2023). This literature review synthesizes existing research on DHTs in DCTs, with a comparative analysis of India and Ireland, focusing on their regulatory landscapes, technological and operational challenges, the role of Contract Research Organizations (CROs), and emerging trends. Additionally, I will explore the current digital health landscape of both countries, examine the types of DHTs used in both regions, and highlight case studies showcasing real-world applications of digital health technologies in decentralized trials. By examining these factors, this review aims to highlight both the opportunities and challenges associated with implementing digitalized clinical trials and inform strategies for improving clinical research efficiency on a global scale.

## 2.2 TRADITIONAL CENTRALIZED VS. DECENTRALIZED CLINICAL TRIALS

### a) Centralized Clinical Trials

Clinical trials are considered as cornerstone for developing new drugs. According to WHO, clinical trials are defined as a type of research that studies new tests and treatments and evaluates their effects on human health outcomes(WHO, 2025a). Among clinical rials, the centralized clinical trials are considered as the traditional model of clinical research. Centralized clinical trials refer to studies in which participants are assessed and monitored at a single, centralized location—typically a laboratory or clinical research facility. This conventional model has long been the standard in the pharmaceutical industry, relying on in-person evaluations conducted by a dedicated researcher affiliated with the sponsoring organization. However, one of the major challenges with centralized trials is their limited reach in patient recruitment. Traditional clinical trials rely on centralized sites for patient visits, data collection, and monitoring, which can be logistically challenging. Many potential participants are either unable or unwilling to travel significant distances to attend site visits, which significantly narrows the recruitment pool. This limitation can lead to delays in the study timeline, as enrollment takes longer than expected(Fogel, 2018). If participant numbers remain below target, the trial may experience setbacks in funding, and in some cases, studies may be terminated entirely if sponsors withdraw their support (Friedrich, 2022). Apart from these, centralized clinical trials are also complex, time-consuming, expensive, and burdensome for both participants and staffs (Califf and Rutherford, 2018). In contrast, DCTs leverage DHTs such as telemedicine, e-consent, and remote monitoring to decentralize trial operations, enabling patients to participate from their homes(Jean-Louis and Seixas, 2024). DHTs, including wearable devices, mobile apps, and sensors, allow real-time collection of data directly from patients, reducing the need for frequent site visits and improving accessibility(FDA, 2024a)

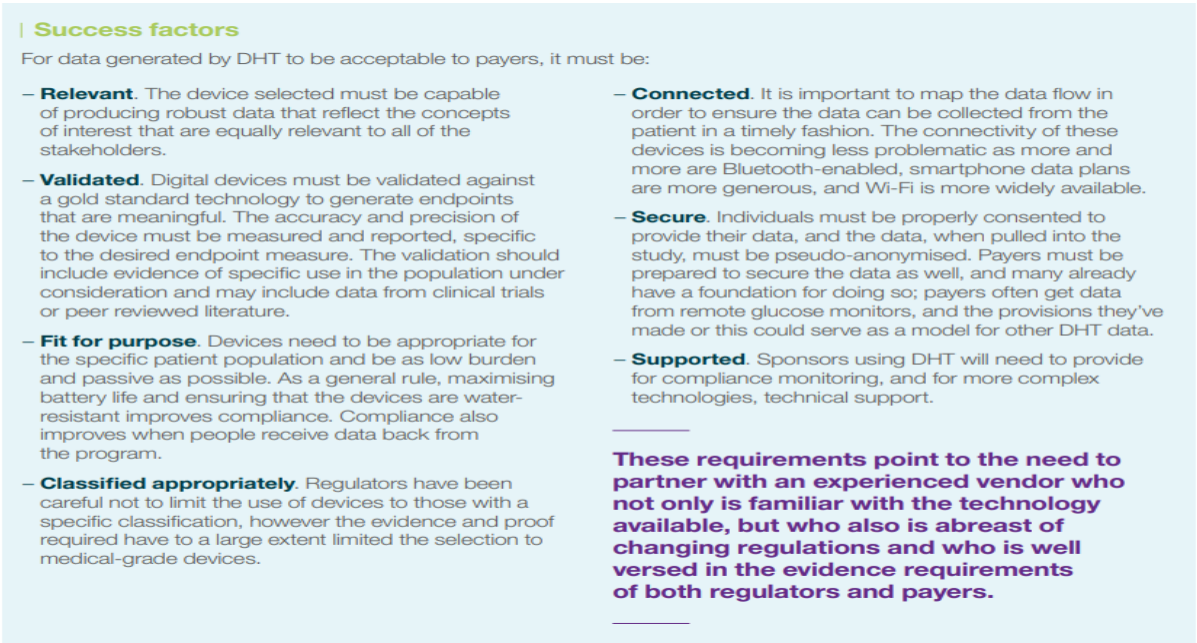
### b) Decentralized Clinical Trials

Decentralized Clinical Trials (DCTs) represent a transformative approach to conducting clinical research by utilizing digital health technologies (DHT) like telemedicine, mobile health apps, remote monitoring devices to perform trial-related activities outside traditional clinical settings like participants home, a local health care facility, or a nearby laboratory (Friedrich, 2022; Mason Hayes & Curran, 2023). DCTs aim to enhance patient engagement, improve

accessibility, and streamline data collection by bringing the trial to the participant rather than the reverse(de Jong *et al.*, 2022; FDA, 2024b).

The primary application of DCTs is to increase the inclusivity and reach of clinical research. By minimizing the need for participants to travel to central locations, DCTs can enroll a more diverse population, including individuals from rural or underserved areas who might otherwise be excluded due to logistical constraints. This inclusivity enhances the generalizability of trial findings, ensuring that results are more representative of the broader patient population(FDA, 2024b).

Additionally, DCTs facilitate the collection of real-world data through digital health technologies, such as wearable devices, activity trackers, and mobile health applications(Oracle, 2025). These tools enable the continuous monitoring of participants in their natural environments, providing a more comprehensive understanding of treatment effects and patient experiences(Cave *et al.*, 2019). According a whitepaper released by ICON, the data generated by DHTs is acceptable only if they are relevant, validated, fit for purpose of the study (See Figure 2.2.1)



**Success factors**

For data generated by DHT to be acceptable to payers, it must be:

- **Relevant**. The device selected must be capable of producing robust data that reflect the concepts of interest that are equally relevant to all of the stakeholders.
- **Validated**. Digital devices must be validated against a gold standard technology to generate endpoints that are meaningful. The accuracy and precision of the device must be measured and reported, specific to the desired endpoint measure. The validation should include evidence of specific use in the population under consideration and may include data from clinical trials or peer reviewed literature.
- **Fit for purpose**. Devices need to be appropriate for the specific patient population and be as low burden and passive as possible. As a general rule, maximising battery life and ensuring that the devices are water-resistant improves compliance. Compliance also improves when people receive data back from the program.
- **Classified appropriately**. Regulators have been careful not to limit the use of devices to those with a specific classification, however the evidence and proof required have to a large extent limited the selection to medical-grade devices.
- **Connected**. It is important to map the data flow in order to ensure the data can be collected from the patient in a timely fashion. The connectivity of these devices is becoming less problematic as more and more are Bluetooth-enabled, smartphone data plans are more generous, and Wi-Fi is more widely available.
- **Secure**. Individuals must be properly consented to provide their data, and the data, when pulled into the study, must be pseudo-anonymised. Payers must be prepared to secure the data as well, and many already have a foundation for doing so; payers often get data from remote glucose monitors, and the provisions they've made or this could serve as a model for other DHT data.
- **Supported**. Sponsors using DHT will need to provide for compliance monitoring, and for more complex technologies, technical support.

**These requirements point to the need to partner with an experienced vendor who not only is familiar with the technology available, but who also is abreast of changing regulations and who is well versed in the evidence requirements of both regulators and payers.**

*Figure 2.2-1Success factors for DHTs (ICON, 2021)*

Although decentralized clinical trials are gaining momentum, they remain relatively new and require continued guidance and support from regulatory authorities to fully realize their potential.(Friedrich, 2022)

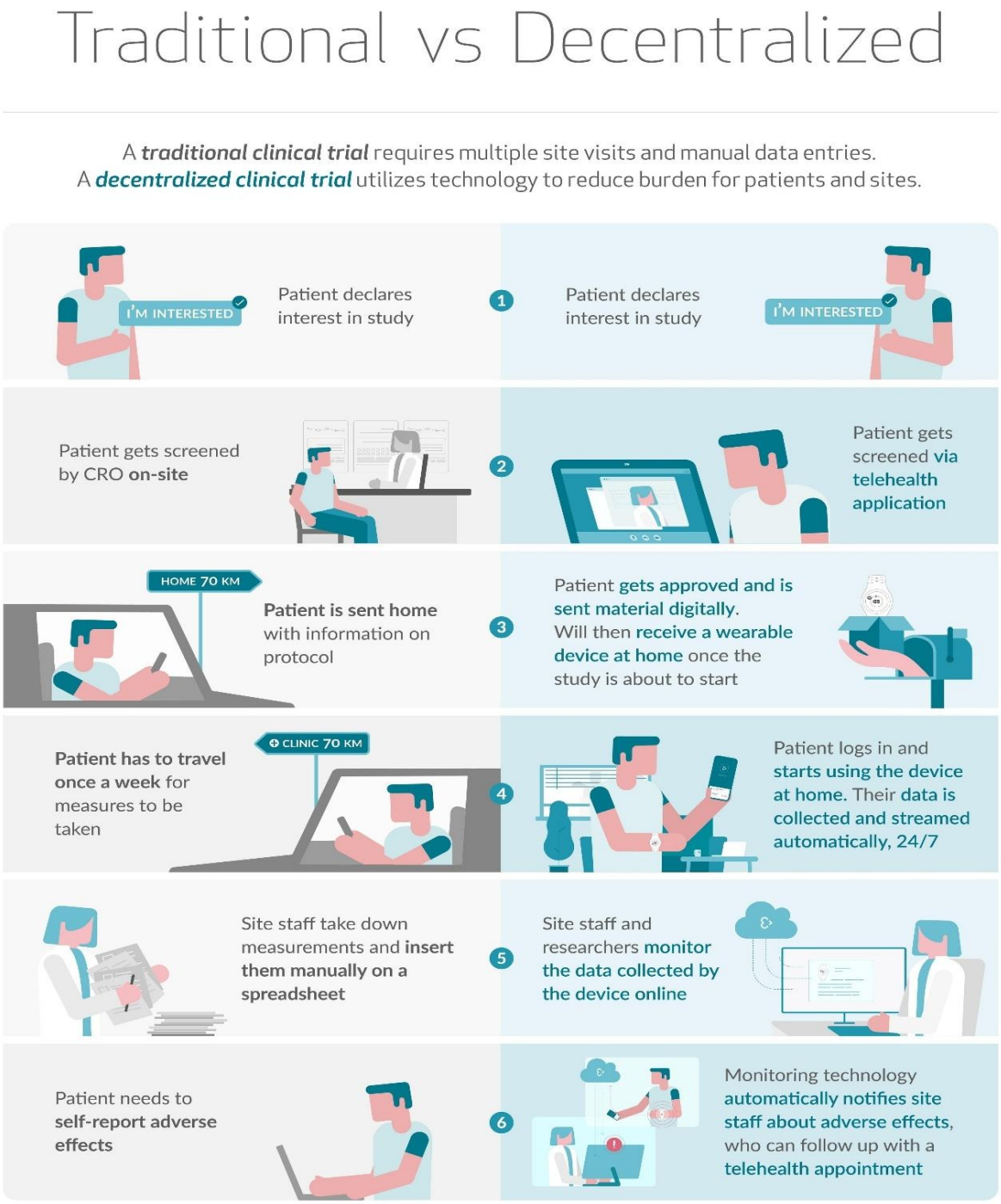



*Figure 2.2-2Traditional Clinical trials versus Decentralized clinical Trials(Empatica, 2021)*

*Table 2.2-1Benefits and Challenges of Decentralized Clinical Trials ((Mason Hayes & Curran, 2023)*

| BENEFITS | CHALLENGES |
|---|---|
| **Improved participation:** DCTs can reduce travel burden on patients by allowing them to participate in the trial from their homes, thus increasing participation rates. This can also potentially lead to a more varied pool of potential participants located further away from a hospital or lab where investigators are based<br><br>**New sources of data:** DCTs can allow fewer study personnel to gather objective data in real time, reducing reliance on a larger number of investigators to perform participant evaluations. Effectively managed, this has the potential to reduce the variability of data collected and allow for faster responses to safety issues<br><br>**Reduced costs**: DCTs have the potential to reduce the overall costs of clinical trials by reducing reliance on fixed physical sites, reducing the number of site visits, and decreasing the need for on-site monitoring<br><br>**Improved efficiency:** DCTs offer the possibility of accelerating trial timelines in appropriate cases by eliminating travel time, reducing data entry time, and allowing for real-time monitoring | **Patient safety and data integrity:** DCTs must have robust systems in place to ensure that patient safety and data integrity are maintained, including appropriate oversight, monitoring, and data management systems<br><br>**Adequate oversight:** Regulators must ensure that DCTs are appropriately designed and executed, and that sufficient oversight is provided to ensure that the trial meets regulatory requirements<br><br>**Data privacy:** DCTs must adhere to strict data privacy regulations, including GDPR compliance, to protect patient privacy and ensure that patient data is not compromised<br><br>**Trial consistency:** DCTs may introduce additional sources of variability, such as differences in digital tools and devices or internet connectivity, which may impact trial results and the credibility of trial results |

### c) Growth of DHTs in Decentralised Clinical Trials

The adoption of digital health technologies (DHTs) in clinical trials has grown rapidly, propelled by the global need for more patient-centric, flexible, and cost-effective research models. The COVID-19 pandemic served as a catalyst for this transformation, disrupting traditional clinical trial operations and compelling stakeholders to embrace remote solutions. Restrictions on in-person healthcare delivery prompted providers to overcome longstanding barriers to technology adoption (Winstanley et al., 2020) and to explore innovative virtual tools

for healthcare and clinical research continuity (Iyengar et al., 2020). As a result, many clinical investigators and sponsors either temporarily suspended trials or restructured them using digital approaches such as remote recruitment, telemedicine visits, and electronic informed consent (Noonan & Simmons, 2020). Regulatory agencies responded proactively: both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) issued guidance recommending the use of alternative, decentralized approaches to maintain participant safety and ensure trial integrity (U.S. FDA, 2020; EMA, 2020). Similarly, India's Central Drugs Standard Control Organization (CDSCO) and Indian Council of Medical Research (ICMR) released advisories to facilitate remote monitoring, electronic consent, and digital data capture during the pandemic.

These regulatory shifts have laid the groundwork for the long-term integration of decentralized (de Jong *et al.*, 2021).

A study conducted by THREAD platform revealed stark differences in clinical trial performance during the pandemic.

Both traditional and decentralized trials experienced a steep decline in participant enrollment from February to April 2020. However, by May 2020, only decentralized trials recovered and exceeded pre-COVID recruitment rates, while traditional trials struggled to regain momentum and never returned to pre-pandemic levels. **(Figure 2.2.3**).

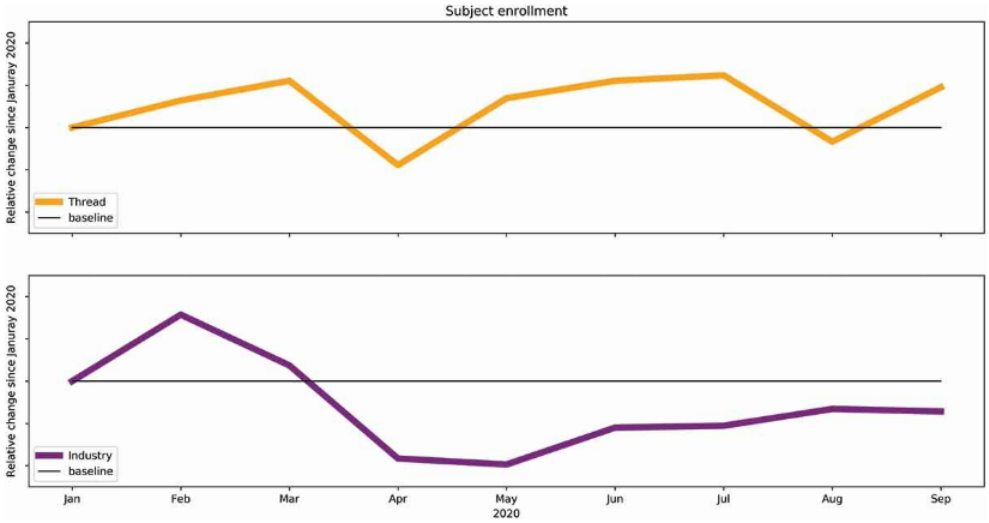



*Figure 2.2-3NORMALIZED PARTICIPANT ENROLLMENT FOR DECENTRALIZED TRIALS (TOP LINE) COMPARED TO INDUSTRY BENCHMARKS DURING THE INITIAL COVID-19 PANDEMIC OUTBREAK (THREAD, 2022)*

This data underscores the resilience of decentralized trials during the pandemic, enabled by DHTs. The ability to conduct trials remotely not only maintained participant engagement but also expanded access to diverse populations, highlighting the potential of DCTs to transform clinical research in a post-pandemic world (Thread, 2022).

Whether COVID-19 will serve as a permanent turning point for the normalization of decentralized clinical trials (DCTs) remains to be seen; however, emerging industry data suggests a sustained movement in that direction. A 2020 report by Jefferies research firm projected that 25% of all clinical trials would be decentralized by 2025, reflecting a 60% compound annual growth rate. Additionally, half of the surveyed Clinical Research Organizations (CROs) anticipated that decentralized elements would become a standard component of most future trials(Price *et al.*, 2021). McKinsey & Company's 2020 survey of investigators from the UK, US, and France revealed widespread expectations for continued use of telemedicine and remote visits beyond the pandemic(Mckinsey, 2021). These trends are reshaping clinical trial expectations, with participants increasingly favoring digital engagement over traditional in-person visits and paper-based processes(Xue *et al.*, 2020). A clear example is the University of Cambridge's HEAL-COVID study, which employed a hybrid model combining in-hospital recruitment with smartphone app-based symptom tracking and integration of real-world data from the NHS digital platform. This rapid shift, particularly within traditionally conservative systems like the UK's NHS, demonstrates that many barriers to DHT adoption can be overcome with adequate motivation and regulatory support.(Le Page *et al.*, 2021)

## 2.3 DIGITAL HEALTH TECHNOLOGIES

The rapid evolution of Digital Health Technologies (DHTs) is transforming the design and execution of clinical trials. Innovations including telemedicine, wearable devices, mobile health apps, artificial intelligence (AI), machine learning (ML), and blockchain are enabling more efficient and patient-centric trial models (FDA, 2024b) . These technologies are being applied across the entire clinical trial process, from drug development to data collection and management, revolutionizing how trials are conducted (Oracle, 2020).

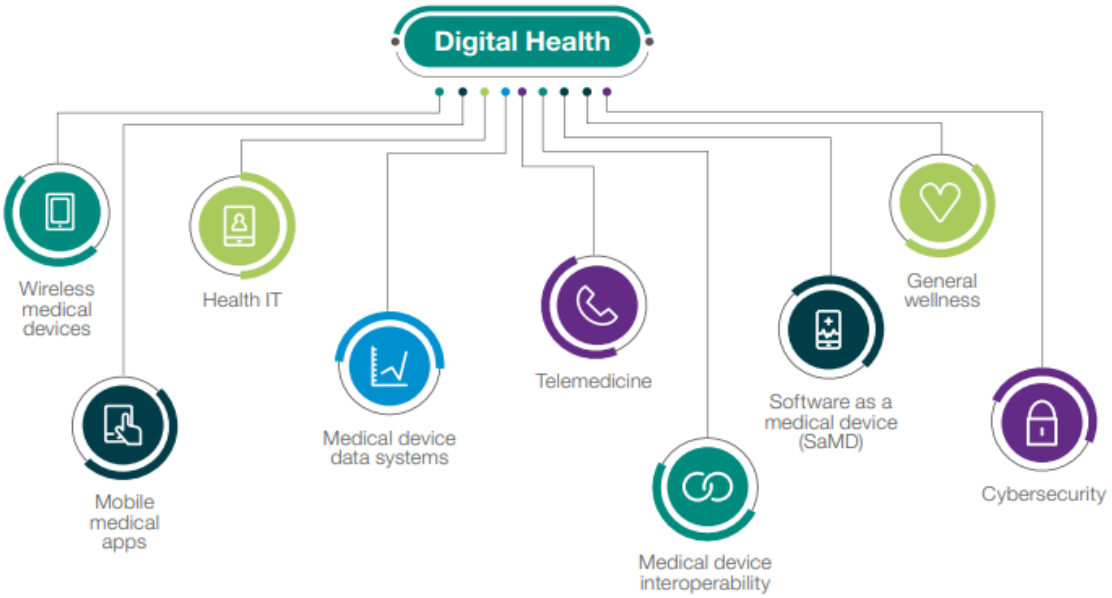



*Figure 2.3-1Digital health technologies(FDA 2018)*

## Telemedicine

Telemedicine is transforming the landscape of clinical trials by enabling remote participation, data collection, and monitoring, thus offering significant advantages over traditional site-based models(Cummins *et al.*, 2024). Telemedicine supports recruitment, screening, consent, and assessment in decentralized trials. Tools like video conferencing, file transfers, remote surveys, and three-way calls facilitate engagement across distances. (Rutkove et al., 2020).

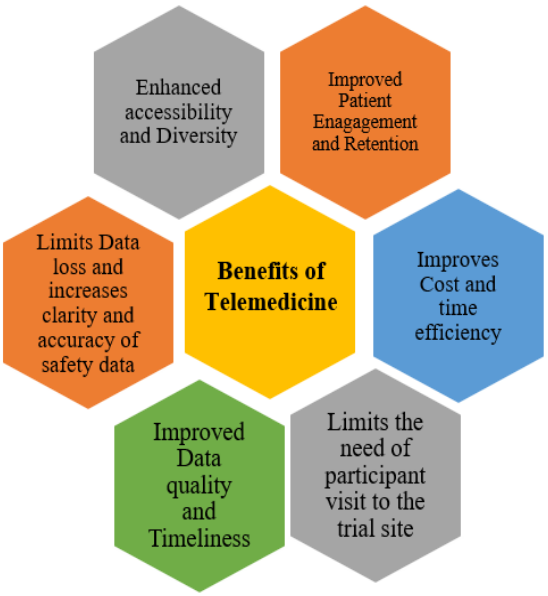



*Figure 2.3-2Benefits of Telemedicine (image created by author)*

**Applications of Telemedicine in Clinical Trials (Figure 2.3.3)**

- Remote Recruitment and Consent: Telemedicine allows researchers to recruit participants from diverse geographic locations and obtain informed consent via secure digital platforms, reducing barriers to enrollment.
- Virtual Visits and Assessments: Video consultations and telehealth check-ins enable ongoing participant engagement and clinical assessments without requiring travel to sites
- Safety Monitoring: Telemedicine enables timely identification and management of adverse events, enhancing patient safety and adherence to protocols.
- Tele-education and training: Telemedicine platforms facilitate the education and training for trial staff and participants(Meghiref *et al.*, 2022; Cummins *et al.*, 2024; LindusHealth, 2024a)


*Figure 2.3-3Application of Telemedicine in Decentralized Clinical Trials (Cummins et al., 2024)*

**Disadvantages of Telemedicine:**

- **Technology Access:** Successful implementation requires that participants have access to reliable internet and suitable devices, as well as sufficient digital literacy
- **Regulatory and Ethical Issues:** Ensuring data privacy, security, and compliance with regulatory standards is critical. Collaboration among sponsors, CROs, and regulatory bodies is necessary to develop robust guidelines.
- **Support Infrastructure:** Additional support may be needed for participants to set up and troubleshoot telemedicine tools, which can increase staff workload.(LindusHealth, 2024a; Cummins *et al.*, 2024)

*Table 2.3-1Examples of Telemedicine Platforms (B, 2022; Sullivan, 2023; Medidata, 2025)*

| **Telemedicine Platforms Currently In Use** | |
|---|---|
| **India** | **Ireland** |
| Practo, MFine, Lybrate, Medidata | Zoom for Healthcare, Whyze Health |

## Wearables

The integration of wearable technology in clinical trials has emerged as a transformative force in modern clinical research, particularly within the framework of decentralized clinical trials (DCTs) (ICON, 2020). Wearables, defined as remote monitoring devices worn by patients to collect health-related data, are increasingly used to capture continuous, real-time physiological metrics such as heart rate, physical activity, sleep patterns, glucose levels, and oxygen saturation (Figure 2.3.4). Examples include activity trackers (e.g., FitBit), glucose monitors, blood pressure monitors, and spirometers. (FDA, 2024b)

**Types of Wearable Technologies:**

1. Smartwatches- measures heart rate, sleep tracking
2. Fitness Bands/trackers- focus on steps, calorie counts and sleep metrics
3. Biosensor Patches- collect data on vitals like glucose or cardiac rhythms
4. Implantable or Ingestible sensors(Quanticate, 2025)

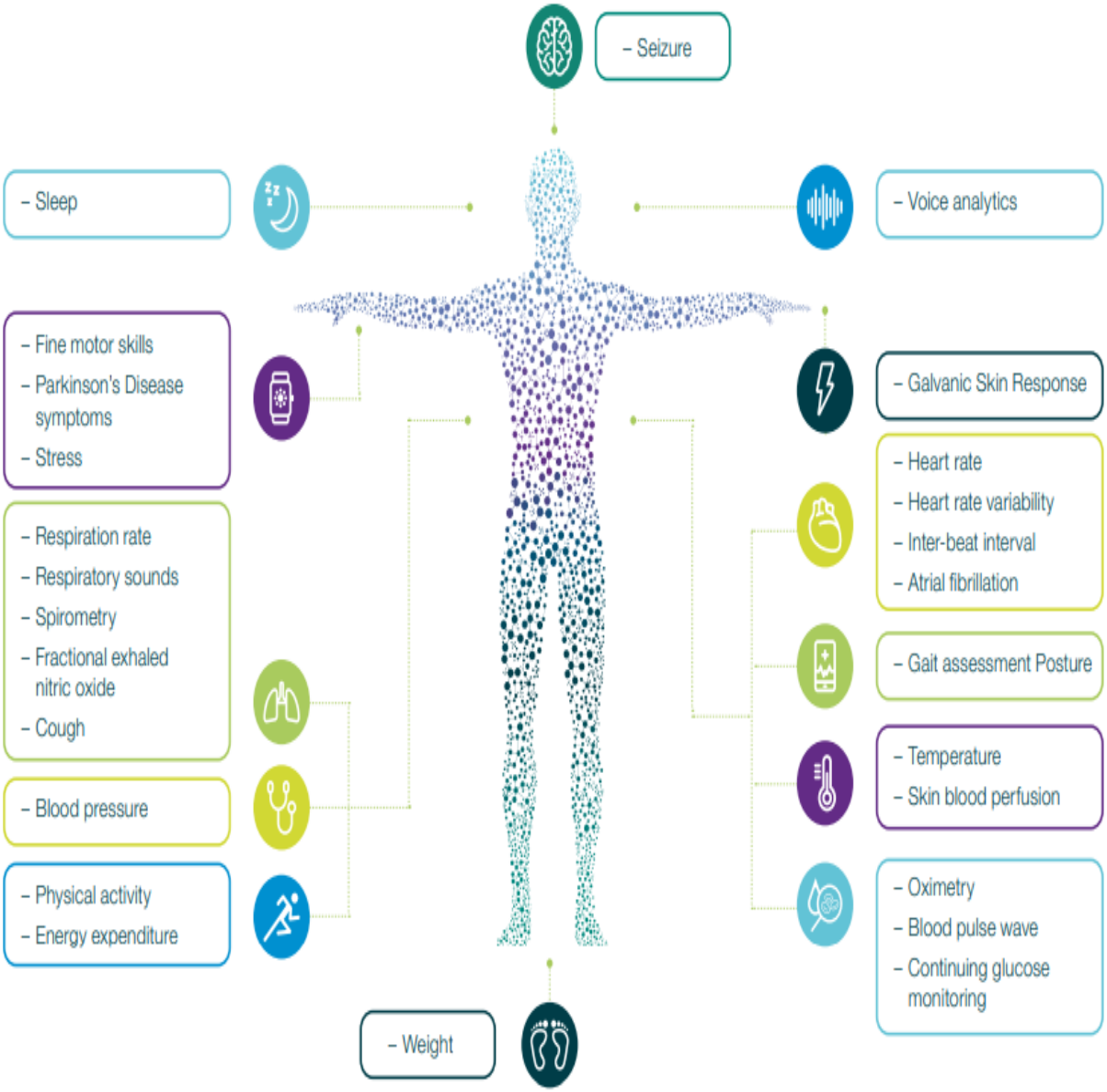



*Figure 2.3-4Endpoints Derived from wearables(ICON, 2020)*

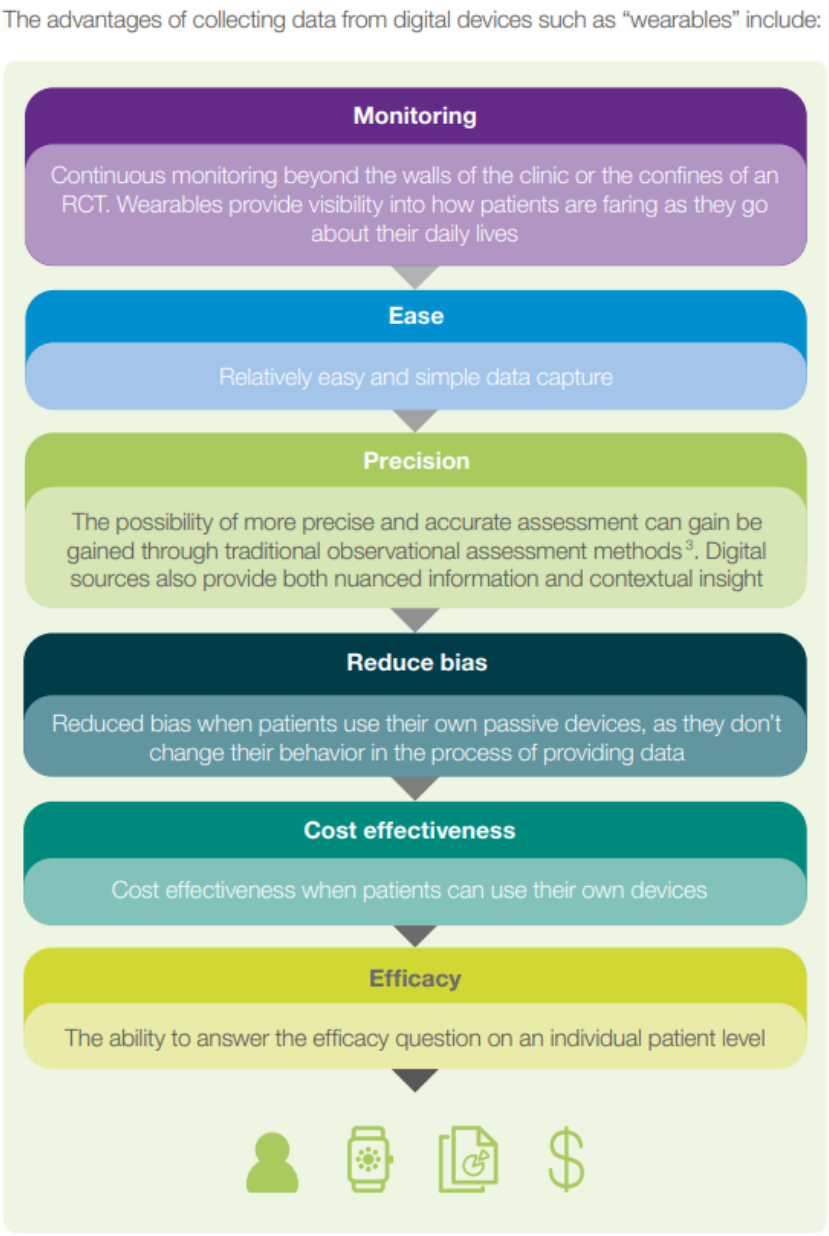



*Figure 2.3-5Advantages of wearables(ICON, 2021)*

**Disadvantages of Wearables**

- Data Accuracy and Validation: Variations in device quality, calibration, and user behaviour may affect reliability, necessitating strict validation protocols.
- Privacy and Security Risks: Wearables collect sensitive health data, requiring compliance with regulations like GDPR (EU), HIPAA (U.S) and other regulations to prevent data breaches.

- Regulatory and Standardization Gaps: There is a lack of harmonised regulations to standardise wearable devices (ICON, 2021; Quanticate, 2025).

*Table 2.3-2Examples of Features of Lifestyle and Remote Monitoring Devices (NSAI, 2025)*

| Feature | Remote Monitoring devices | Examples |
|---|---|---|
| Heart rate | Many smart watches record this parameter.<br>It can also be obtained from phone apps and pulse oximeters. | Apple, Fitbit |
| Saturated Oxygen | It can be captured from self-contained finger probes and some smart watches. | Pulse-oximeters |
| Blood pressure | Many stand-alone devices are available, including self-contained devices where the pump and display are built into the arm piece.<br>Some devices also connect with apps | Ambulatory Blood pressure monitors |
| ECG | Some smart watches capture ECG, and associated apps can detect Atrial fibrillation<br>(Afib) | Nasiff Cardiocard, Welch Allyn CP200 |
| Heart Rate Variability | Smart watches, smart rings, chest-straps, and apps | Apple, Fitbit, Garmin |
| Sleep | Smart watches, smart rings, under-mattress sensors, and bedside balistography devices | Philips Respironics |
| Seizure Sensor | Under-mattress sensor. | Epilog, Embrace 2 |

## Mobile Health Technologies

According to WHO Global Observatory for eHealth, mHealth-a component of eHealth- is a medical and public health practice supported by mobile devices—including smartphones, wearables, and wireless sensors—mHealth utilizes core functionalities like voice, messaging, GPS, and advanced sensors (accelerometers, gyroscopes, cameras) to enable real-time, remote health monitoring(Kakkar *et al.*, 2018; WHO, 2025b).

It helps in participant engagement, data collection, and operational efficiency. They facilitate patient recruitment, reduce site visits through remote monitoring, and improve retention via real-time feedback(Carlo *et al.*, 2019). By capturing continuous, ecologically valid data—such

as motor symptoms in Parkinson's disease (e.g., tremor, gait) or mood fluctuations in depression—mHealth enhances the precision of endpoints while reducing trial costs and duration. Key challenges include validation gaps (e.g., correlation with patient-centered outcomes like quality of life), data privacy concerns, and interoperability issues, technological literacy disparities(Bhavnani *et al.*, 2016; Artusi *et al.*, 2020).

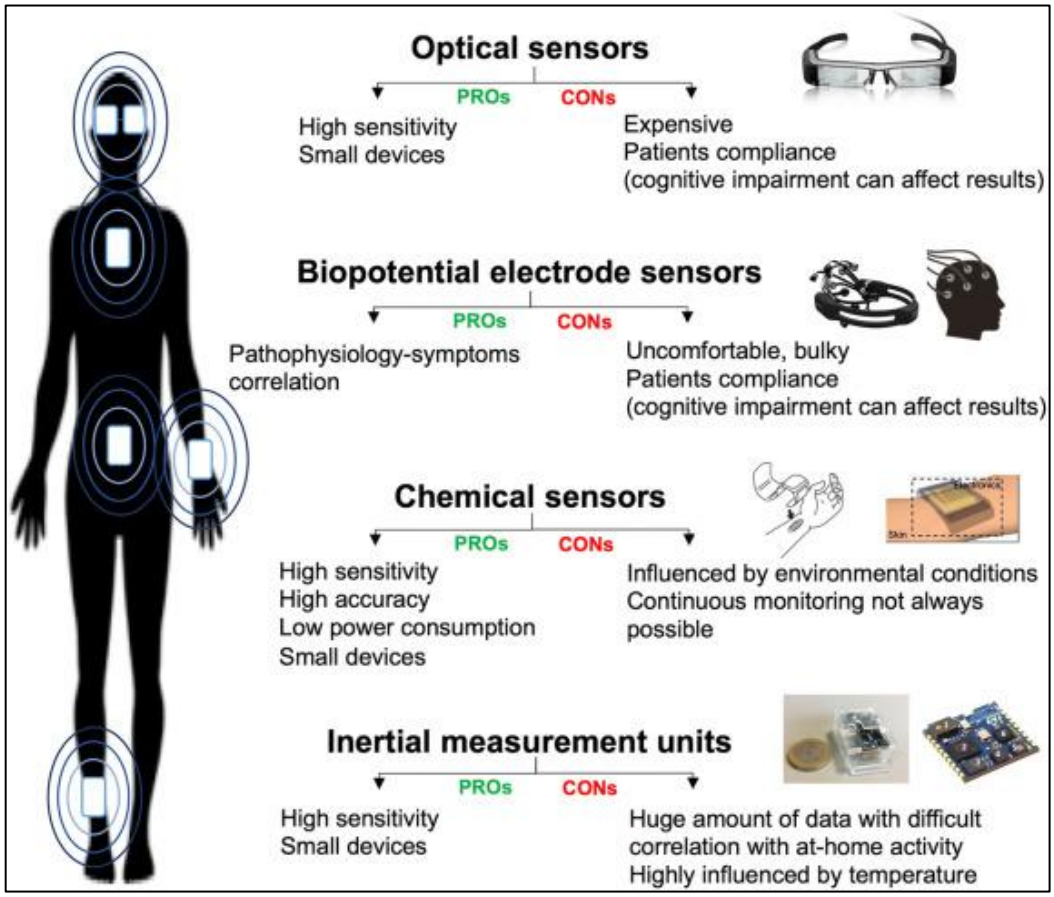



*Figure 2.3-6 Types of mobile health technologies(Artusi et al., 2020)*

## Electronic Consent (eConsent)

Electronic consent (eConsent) has emerged as a solution to the challenges of traditional paper-based informed consent forms (ICFs) in clinical trials. Conventional ICFs are often lengthy, complex, and difficult to understand, leading to poor participant comprehension, administrative errors (such as missing signatures or incorrect versions), and even early trial withdrawals(Chimonas *et al.*, 2023). eConsent addresses these issues by incorporating multimedia elements (videos, audio, interactive graphics), self-paced learning tools, electronic signatures, and version control, all of which enhance understanding and engagement.

According to Eclevar, the top eConsent platforms include Castor EDC, Milo Healthcare, Veeva, Signant Healthcare, and Medidata(Eclevar, 2024). Studies show that eConsent improves comprehension compared to paper forms, particularly through multisensory learning, as cognitive theories suggest that combining visual and auditory information aids retention(Almeida-Magana *et al.*, 2022). Patients, including older adults, report higher satisfaction and usability with eConsent, despite potential technology literacy barriers, as intuitive design and training can mitigate these challenges. Additionally, eConsent reduces administrative errors, improving regulatory compliance by ensuring accurate documentation. (Cragg *et al.*, 2024). However, the effectiveness of eConsent depends on well-structured content—simply digitizing a poorly written form will not improve outcomes. Future research should explore optimal multimedia use, cognitive load management, and long-term retention effects. Overall, eConsent represents a significant advancement in clinical trial ethics, offering a more engaging, accessible, and compliant approach to informed consent(Almeida-Magana *et al.*, 2022).

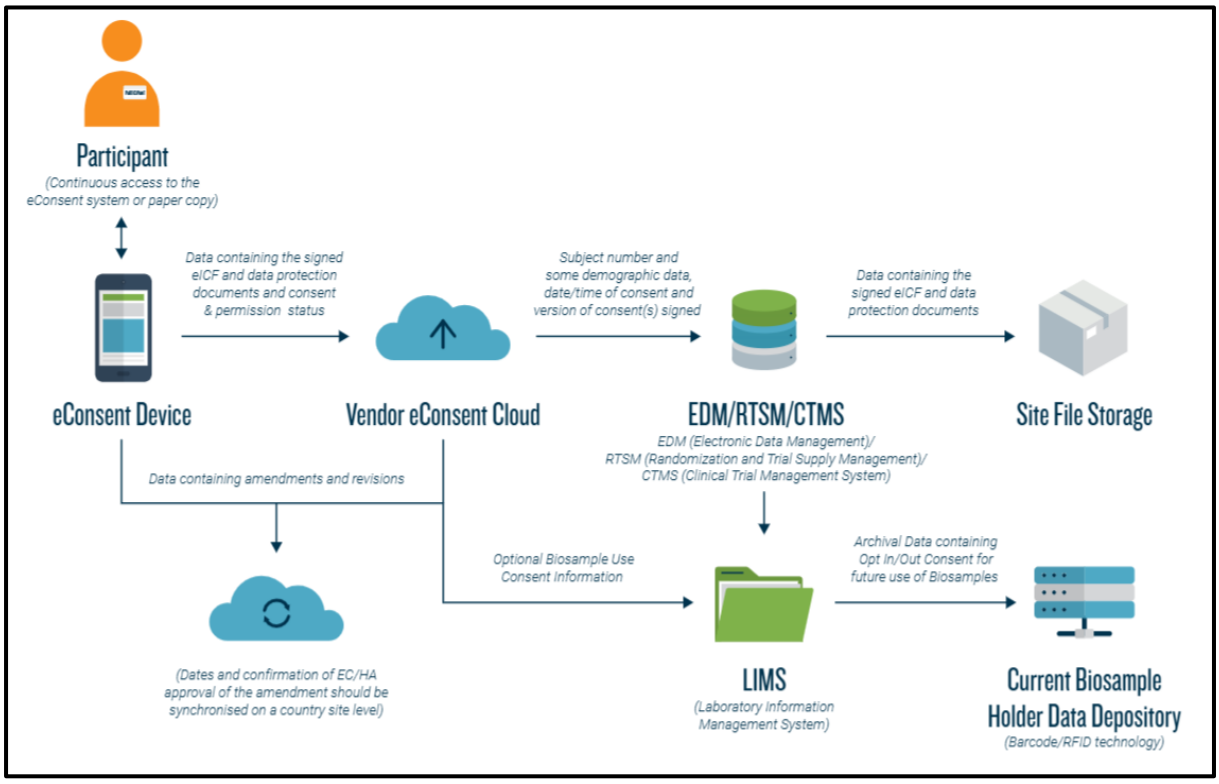



*Figure 2.3-7 e-consent platform(ICON, 2020)*

| *Advantages* | *Disadvantages* |
|---|---|
| Avoids physical attendance | Patients may be unfamiliar with electronic device use—increasing the digital divide and decreasing diversity of recruitment |
| Requires fewer human resources | Privacy concerns if not properly set-up |
| Requires less physical space | Could introduce selection bias towards younger patients and those with higher education |
| Can be deployed to any number of devices | May decrease equitable access to trials across the socioeconomic spectrum |
| Allows patients to answer in a safe space | Relies on patient access to electronic devices, email, and Internet connection |
| Can adapt to patient-specific disabilities | |
| Scalable | |
| Reduces travel-associated costs and reduces carbon footprint | |
| Reduces risk of contagion of infectious diseases | |
| Integrated hard stops prevents missing fields | |
| Increases traceability | |
| Removes postage cost | |
| Removes possibility of transcription errors | |
| Absence of time pressure | |

*Figure 2.3-8Advantages and disadvantages of e-consent platforms(Almeida-Magana et al., 2022)*

## Real-World Data from Electronic Health Records and Registries

Real-World Data (RWD), encompassing EHRs, administrative claims, and patient registries, provides opportunities for pragmatic trials and faster recruitment (FDA,2020 ; Cowie et al., 2017). By utilizing the vast data stored in EHR systems, researchers can rapidly identify suitable participants and tailor the recruitment strategies. According to the American Hospital Association, over 96% of hospitals in the United States have adopted EHR systems, emphasizing their major role in modern healthcare (ICON, 2025).

However, challenges such as data inconsistency, missing fields, and integration complexity must be addressed (Ma et al., 2019; Obeid et al., 2017).

## Artificial Intelligence in Clinical Trials

AI—including machine learning and deep learning—is increasingly applied in trial design, patient identification, and monitoring (Mak & Pichika, 2019; Jang, 2019). It offers predictive

analytics that can optimize patient selection and treatment matching. Studies demonstrate AI's diagnostic potential (Lin et al., 2019) and use in personalized dosing regimens (Roggeveen et al., 2019; Wijnberge et al., 2020), showcasing its ability to enhance trial outcomes and efficiency.

### Blockchain Technology for Data Management

Blockchain technology is a rapidly emerging tool that enhances data transparency, traceability, and security—all critical in clinical research. Mayer et al. (2018) emphasized blockchain's potential for secure health information exchange and patient-controlled privacy. For clinical trials, it provides tamper-resistant audit trails and strengthens data integrity (Osipenko, 2019; Benchoufi & Ravaud, 2017). A study by IBM highlights that this technology can significantly reduce data breaches and enhance the overall security of sensitive healthcare information(ICON, 2025).

## 2.4 CURRENT DIGITAL HEALTH LANDSCAPE IN INDIA AND IRELAND

### India: Emerging Potential with Persistent Barriers

India has emerged as a significant global hub for clinical research, with its clinical trials market valued at approximately USD 1.55 billion and projected to reach USD 8.36 billion by 2029, growing at a compound annual growth rate (CAGR) of 8.64%. This remarkable growth is attributed to a combination of factors, including a large and diverse patient population, cost-effective trial execution, streamlined regulatory processes, increased R&D investment, and a skilled biomedical workforce. Key contributors to the ecosystem include domestic pharmaceutical companies such as Cipla, Sun Pharma, and Dr. Reddy’s Laboratories, global players like Pfizer, Novartis, and Roche, as well as contract research organizations (CROs) including Parexel, IQVIA, and India-based Syngene International. The sector employs over 300,000 professionals across clinical, operational, and administrative roles, with therapeutic focus areas ranging from oncology and infectious diseases to diabetes and cardiovascular conditions(Cliniminds, 2025). However, despite India’s strong positioning in conventional clinical research, the integration of digital health technologies (DHTs) into decentralized clinical trials (DCTs) presents a host of challenges.

A benchmarking report by IQVIA (2022) indicated that India scores low in digital health system maturity, reflecting significant gaps in infrastructure, governance, and digital integration (Figure 8). Although recent efforts by the Central Drugs Standard Control Organization (CDSCO) have introduced preliminary frameworks for decentralized trials, key elements such as telemedicine, eConsent, and remote monitoring remain ambiguously regulated (John et al., 2024). Additionally, infrastructural disparities between urban and rural regions pose substantial limitations, with low internet penetration, unreliable power supply, and limited digital literacy hindering the scalability of DCTs in underserved areas (Narayan et al., 2024).

Data protection and cybersecurity also remain critical issues; although the Digital Personal Data Protection Act (2023) marks progress in safeguarding patient information, its implementation is still in nascent stages and lacks standardized enforcement protocols (Narayanan & Krishna, 2024). While India accounts for approximately 8% of global clinical trial activity and government initiatives such as the National Clinical Research Network aim to foster innovation, the successful adoption of DHTs will require harmonized digital regulations, robust infrastructure development, and capacity-building across stakeholders to ensure inclusive, efficient, and ethically sound decentralized trial models.

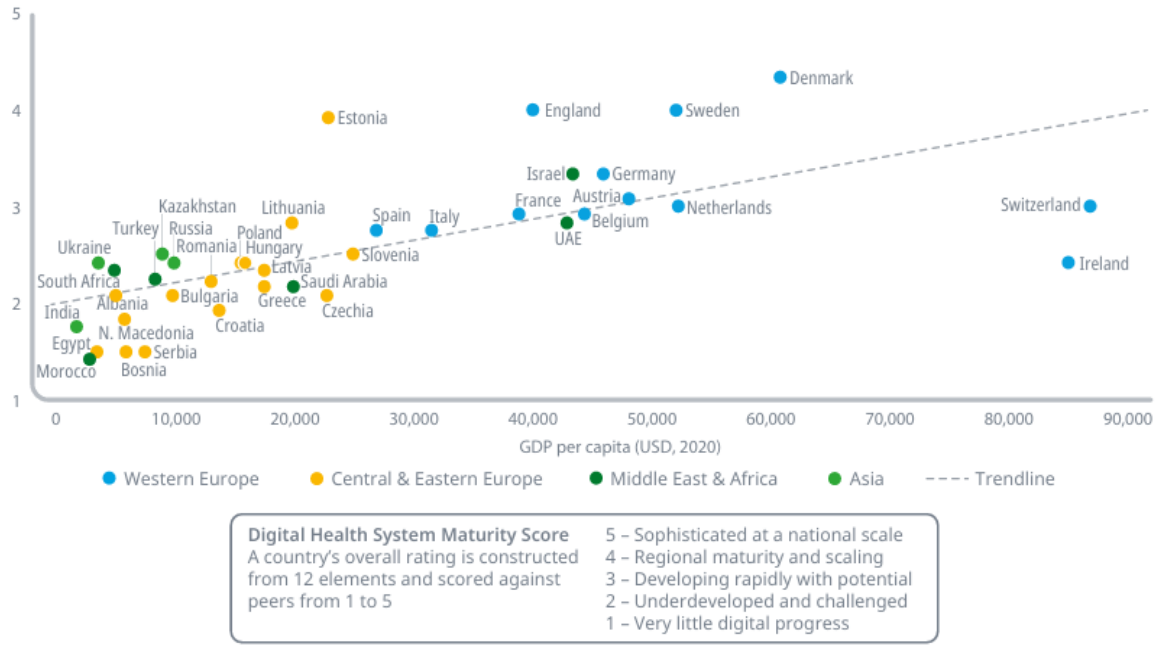



*Figure 2.4-1Digital Health System Maturity Scores(IQVIA, 2022)*

**Ireland: current Irish digital landscape**

Ireland, known for its thriving pharmaceutical and med-tech sectors, holds strategic importance in global clinical research. Since the introduction of the *eHealth Strategy for Ireland* in 2013, the country has made concerted efforts to enhance its digital health infrastructure and foster an integrated healthcare ecosystem. Despite this progress, Ireland's digital health system remains fragmented and underutilized in the context of decentralized trials.

The COVID-19 pandemic brought both challenges and opportunities for Ireland's digital health evolution. It exposed longstanding deficiencies in real-time health data collection and interoperability, but also acted as a catalyst for rapid innovation. Emergency measures during the pandemic led to the deployment of cloud-based data platforms, AI-driven health chatbots, and telemedicine services to manage public health demands effectively (Walsh et al., 2021).

Nonetheless, according to the Health Service Executive (HSE, 2024), Ireland continues to face significant barriers to achieving digital health maturity. Despite ranking 5th on the EU's Digital Economy and Society Index (DESI), Ireland was rated last among developed countries in terms of digital health readiness. Key obstacles include limited access to digital tools, inadequate AI integration, and continued reliance on paper-based record systems that hinder coordinated, patient-centered care. The lack of fully integrated electronic health records (EHRs) and insufficient digital infrastructure impede the wider deployment of remote monitoring, eConsent, and digital therapeutics—crucial components of DCTs.

While national investment in digital health has grown, it is yet to reach the scale required for transformational change. The HSE emphasizes the need for strong governance, sustained financial commitment, and incremental innovation to bridge the digital divide and support scalable, community-based healthcare models (HSE, 2024). Addressing these systemic issues will be critical to improving Ireland's readiness for DCTs and realizing the full potential of digital health.

*Table 2.4-1Comparative Analysis of Ireland and India( IQVIA,2022)*

| Aspect | Ireland | India |
|---|---|---|
| **Digital Infrastructure** | Moderate; urban areas are better connected | Fragmented, rural-urban digital divide |
| **National Strategy** | Present but slow in implementation | NDHM in progress, not fully deployed |
| **Regulatory Readiness** | Evolving, some EMA alignment | Developing; lacks clear DCT and DHT guidelines |
| **EHR Usage** | Partially implemented | Limited, early stages |
| **Telehealth Adoption** | Grew during COVID-19; uneven across regions | Expanded during the pandemic; strong government push |
| **Barriers** | Interoperability, clinician training, and public trust | Infrastructure, digital literacy, policy gaps |

*EMA- European Medical Agency  NDHM- National Digital Health Mission*

## 2.5 REGULATIONS AND GUIDELINES GOVERNING THE IMPLEMENTATION OF DHTS IN CLINICAL TRIALS

### India's Framework for Digital Tools in Clinical Research

India's regulatory landscape for digital tools in clinical research is governed by a blend of established and evolving legislation. The Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945 form the legal foundation for clinical research oversight, while the New Drugs and Clinical Trial Rules, 2019 provide specific guidance on the approval and conduct of clinical trials involving digital technologies (ClinRegs, 2024). Devices like wearables are regulated under the Medical Devices Rules, 2017 .

Ethical guidance is anchored in the ICMR National Ethical Guidelines (2017), complemented by the GCP Guidelines from CDSCO, which are currently being revised to reflect digital integration. Clinical trials using DHTs require approval from the Drugs Controller General of India (DCGI) and ethics clearance from registered Ethics Committees (ECs), which assess data protection and ethical compliance  (Desai, 2025). Electronic informed consent (e-consent) is permissible if it meets privacy and comprehension standards (ClinRegs, 2024), while upcoming GCP amendments stress validation of electronic data capture (EDC) systems .

Data privacy is primarily regulated under the Information Technology Act, 2000 and the SPDI Rules, mandating encryption, secure access, and audit trails. The Digital Personal Data Protection (DPDP) Act, 2023 introduces key obligations for stakeholders such as CROs and sponsors, now classified as Data Fiduciaries. They must implement security safeguards, provide privacy notices in regional languages, and report breaches. Significant Data Fiduciaries are also required to appoint Data Protection Officers and conduct impact assessments (Iyer *et al.*, 2025; Ministry of Electronic and IT, 2025).

Additional oversight for telemedicine is provided under the Telemedicine Practice Guidelines, 2020, which mandate informed consent and secure communication protocols (Narayanan and Krishna, 2024). Trial registration for digital tools as medical devices is required with the Clinical Trials Registry of India (CTRI), and trial records must be maintained for a minimum of seven years.

While progressive, India's framework still lacks comprehensive coverage in areas such as mHealth and alignment with global standards like the EU GDPR. The DPDP Act remains narrower in scope, lacking specific safeguards for sensitive health data compared to GDPR's extensive protections (Jain, 2023). Nevertheless, initiatives like the Ayushman Bharat Digital Mission and forthcoming DPDP Rules (2025) signal continued progress toward ethical and secure digital research environments.

*Table 2.5-1Indian Policies affecting the digitalization of healthcare (Jain, 2023)*

| Type of Regulation | Title of Regulation | Date Effective | Relevant Clauses |
|---|---|---|---|
| **Law** | The Drugs and Cosmetics Act ("D&C Act") | 10 April 1940 | — |
| **Law** | Information Technology Act and Rules (IT Act) | 9 June 2000 | Section 2(w), Section 43A, Section 79 |
| **Regulations** | The Clinical Establishments (Registration and Regulation) Act | 9 August 2010 | Section 38(1) and 38(2) |
| **Law** | The Information Technology Reasonable security practices and procedures and sensitive personal data or information Rules ("Data Protection Rules") | 1 April 2011 | Rule 3, Rule 4(1), Rule 5(1), Rule 5(3), Rule 5(7), Rule 7 |
| **National Standards** | The Information Technology (Intermediaries Guidelines) Rules ("Intermediary Guidelines") | 1 April 2011 | Rule 3 |
| **Law** | The Medical Devices Rules ("MDR") | 5 May 2017 | — |
| **Regulations** | DNA Technology (Use and Application) Regulation Bill | 8 July 2019 | — |
| **Regulations** | Digital Personal Data Protection Bill (DPDP Bill) | 18 November 2022 | Clause 8 |

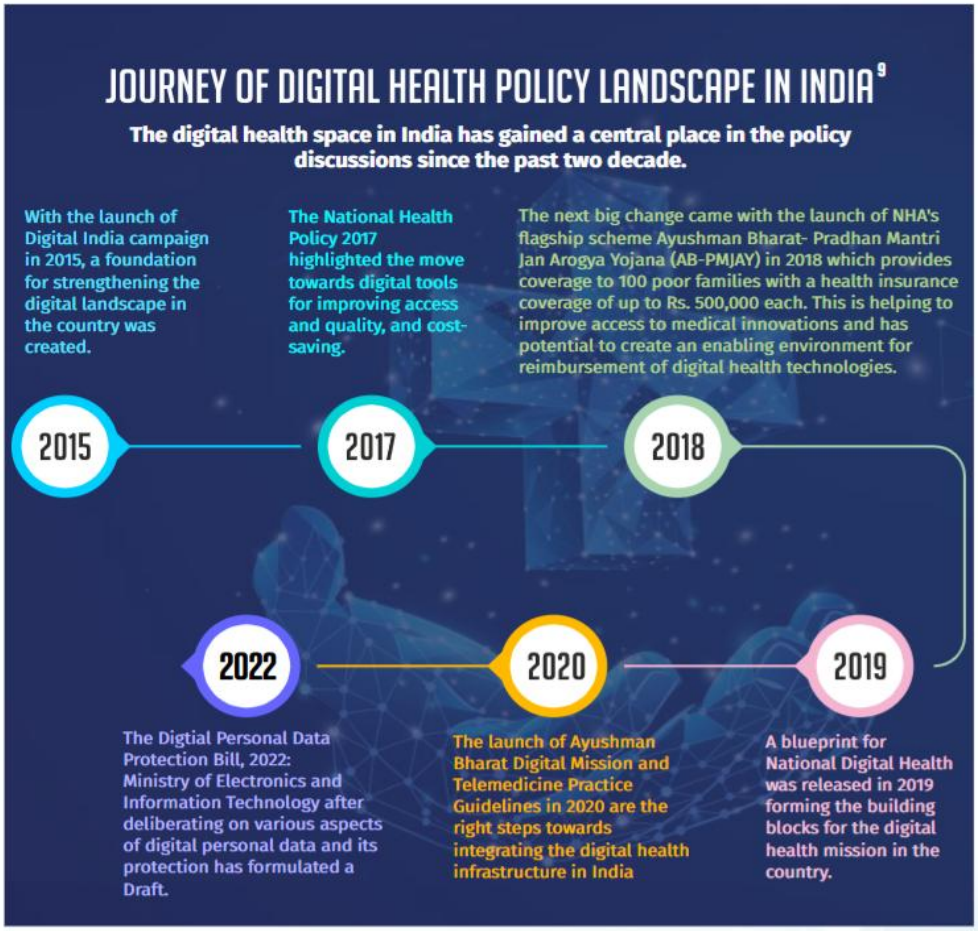



*Figure 2.5-1Digital Health Policy Landscape of India (APACmed, 2022)*

**Ireland's Framework for Digital Tools in Clinical Research**

Ireland's governance of Digital Health Technologies (DHTs) in clinical trials is built upon a robust regulatory system covering data protection, clinical trial oversight, and medical device regulation. At the core is the General Data Protection Regulation (GDPR), which has been directly applicable across the EU since 2018. Supported by Ireland's Data Protection Act 2018, GDPR ensures strict compliance with principles such as lawfulness, data minimization, integrity, and accountability, while granting individuals rights like access, erasure, and data portability(Kavanagh *et al.*, 2022; European Commission, 2024). The Data Protection Commission (DPC) serves as Ireland's supervisory authority and enforces GDPR through audits, investigations, and penalties.

In health research, the Health Research Regulations 2019 impose additional requirements such as mandatory explicit consent for identifiable health data, unless exempted by the Health

Research Consent Declaration Committee. The ePrivacy Regulations further oversee electronic communications and tracking technologies.

For digital tools considered Software as a Medical Device (SaMD), regulation falls under the EU Medical Device Regulation (MDR) and is overseen nationally by the Health Products Regulatory Authority (HPRA). Clinical trial authorization is managed under the EU Clinical Trials Regulation (CTR) using the Clinical Trials Information System (CTIS), while ethical approvals are coordinated through the National Research Ethics Committee for Clinical Trials (NREC-CT)(National Office For Research Ethics Committees, 2022).Requirements include comprehensive informed consent and benefit-risk evaluations.

Ireland also supports digital innovation through participation in the European Health Data Space (EHDS), whose 2025 regulation aims to standardize access and sharing of health data across EU countries(Mason Hayes & Curran, 2023) .The proposed Health Information Bill 2023 further reflects Ireland's intention to modernize health data governance.

While Ireland's regulatory framework is well-aligned with EU standards, successful deployment of DHTs in research requires sponsors and CROs to navigate complex requirements around consent, data security, interoperability, and ethical compliance.


*Figure 2.5-2Clinical Trial Regulation Timeline(National Office For Research Ethics Committees, 2022)*

## 2.6 ROLE OF CONTRACT RESEARCH ORGANISATIONS (CROS) IN CLINICAL TRIALS

Contract Research Organizations (CROs) have become indispensable players in the pharmaceutical and biotechnology industries, offering specialized research services across the drug development pipeline. Their role is becoming even more critical with the rise of digital health technologies (DHTs) and digital therapeutics(Milo Healthcare, 2024).

Contract Research Organization (CRO) sector plays a pivotal role in supporting the pharmaceutical and biotechnology industries, particularly within the clinical trials landscape. With the global contract research market projected to reach USD 90.4 billion by 2030 and growing at a CAGR of 7%, CROs are increasingly becoming essential partners in the drug development value chain(Reilly, 2021; Chopra *et al.*, 2023) (Figure 16). These organizations offer a spectrum of services including discovery research, pre-clinical testing, clinical development (Phases I–IV), and bioequivalence/bioavailability studies to post-marketing surveillance (Government of India (PMCF), 2023; Milo Healthcare, 2024).

The Indian CRO landscape is diverse, encompassing large full-service multinational CROs such as IQVIA and Syneos Health, as well as specialized domestic players like Syngene, Lambda Therapeutic Research, and JSS Medical Research.

**Role of CRO in Clinical Trials**:

1. **Core Contributions to Clinical Trials**: CROs enable pharmaceutical, biotech, and medical device companies to outsource clinical trial management, regulatory affairs, data management, and pharmacovigilance. This outsourcing provides:

- Access to specialized expertise and cutting-edge technologies.
- Operational flexibility and cost efficiency.
- Accelerated development timelines and market entry.

In digital health, CROs are essential for adapting traditional trial designs to new interventions such as mobile apps, wearable devices, and telehealth platforms. Their work ensures that digital therapeutics are evaluated rigorously for safety and efficacy (Reilly, 2021; LindusHealth, 2024b)

2. **Optimizing Clinical Trials for Digital Therapeutics**

Designing clinical trials for digital therapeutics requires specialized approaches. CROs assist by:

- Identifying appropriate patient populations and endpoints.
- Tailoring randomization, control groups, and blinding techniques to the digital context.
- Navigating complex and evolving regulatory frameworks (e.g., FDA's guidelines for software as a medical device).
- Ensuring trials are adequately powered to demonstrate meaningful outcomes.
- Improves management of complex clinical data

CROs also optimize trial efficiency through virtual trials, AI-driven patient recruitment, and real-world evidence (RWE) strategies(Reilly, 2021; Chopra *et al.*, 2023).

3. **Ensuring Data Integrity and Security**

Given the sensitive nature of patient data in digital therapeutics:

- CROs implement secure electronic data capture (EDC) systems.
- They ensure compliance with global data protection laws like HIPAA, GDPR, and other country-specific privacy rules.
- They employ data encryption, audit trails, and strict access controls to maintain confidentiality (Guerchicoff and Ingram, 2021; LindusHealth, 2024b)

These practices are crucial for building trust with patients and regulators.

4. **Nurturing Partnerships with Digital Health Start-ups**

CROs increasingly partner with innovative digital health start-ups to:

- Gain access to technologies like AI, machine learning, wearable devices, and mobile health apps.
- Bring entrepreneurial agility into traditional research models.
- Co-develop customized, patient-centric digital therapeutic solutions.

Start-ups, in turn, benefit from CROs' expertise in trial execution, regulatory navigation, and global market access (Lindus Health, 2024).

5. **Future Outlook**

As digital therapeutics continue to revolutionize healthcare delivery, CROs are evolving into innovation partners rather than just service providers. Their ability to incorporate digital health technologies, optimize trial design, safeguard patient data, and nurture collaborations will define their pivotal role in shaping the future of clinical research.


*Figure 2.6-1Forecasted Global CRO Market for the period 2022-2030(Government of India (PMCF), 2023)*

## 2.7 CHALLENGES IN IMPLEMENTING DHTS IN CLINICAL TRIALS

**Data Security Concerns**: Widespread use of digital tools raises concerns about data misuse, privacy breaches, and unauthorized collection. Ensuring compliance with data protection laws, such as the General Data Protection Regulation (GDPR) in Ireland and the Digital Personal Data Protection Act in India, is critical. For instance, trial sponsors must implement robust data encryption and access control measures to protect patient data. (Whitelaw *et al.*, 2021)

**Digital Security Breaches** – Digital health systems, such as electronic health records (EHRs) and telemedicine platforms, store and transmit sensitive patient information. Unauthorized access or data breaches can lead to the exposure of personal health information (PHI), violating patient privacy (Apostolaros *et al.*, 2020; de Jong *et al.*, 2022; Mason Hayes & Curran, 2023)

**IoT and Device Security -**Internet of Things (IoT) devices, such as wearable health monitors and connected medical equipment, often have weak security measures. These devices can be hacked, leading to data theft or even physical harm to patients.(Keshta and Odeh, 2021)

**Regulatory Compliance**

Another major challenge in using DHTs in DCTs is navigating the complex regulatory landscape. Different regions have varying requirements for data handling, informed consent, and remote monitoring. Harmonizing trial protocols across multiple jurisdictions requires careful planning and a deep understanding of local laws.

**Technological and Infrastructural Barriers**

Not all participants have access to or are comfortable using smartphones, tablets, or wearables. Variations in digital literacy and internet connectivity can create inequities in trial participation and potentially skew study data if not addressed through adequate support and training.(Clohessy *et al.*, 2024)

**Variability in Data Collection**

Remote assessments may introduce inconsistencies in data due to differences in device types, user operation, or environmental conditions. Without standardized tools and procedures, the variability in collected data can affect the reliability and comparability of trial outcomes.

**Limited Investigator Oversight**

With many trial tasks conducted remotely, investigators may find it harder to monitor protocol adherence and participant engagement. This can lead to challenges in maintaining study quality and ensuring compliance with ethical and regulatory requirements.(Mishra, 2022)

**Patient Safety and Data Integrity**

Ensuring patient safety outside of clinical settings requires robust systems for real-time monitoring and communication. Without on-site medical supervision, it becomes critical to have efficient alert mechanisms in place to respond to adverse events promptly and maintain the integrity of collected data (Vayena *et al.*, 2023).

**Trial Consistency**

The use of diverse digital tools and varying internet infrastructure can lead to inconsistencies in how trial procedures are performed. This may impact the standardization of trial conduct and introduce biases that affect the validity and credibility of study results. (Rosa *et al.*, 2021)

## 2.8 FUTURE RESEARCH OPPORTUNITIES

**Promoting Global Collaboration:** WHO emphasizes the need for global collaboration and knowledge transfer in digital health to enhance health outcomes and advance universal health coverage. It promotes collective action among countries and stakeholders to address opportunities, risks, and challenges in digital health adoption (WHO, 2021).

**Patient Perceptions**: Analysing patient perceptions and compliance in DCTs to improve trial design and engagement. For instance, patient surveys can provide insights into the factors influencing participation in DCTs (Apostolaros *et al.*, 2020).

**Hybrid Clinical trials**: Exploring the benefits of hybrid clinical trials combining both traditional centralized and decentralized trials adopted with DHTs. (Mckinsey, 2021)

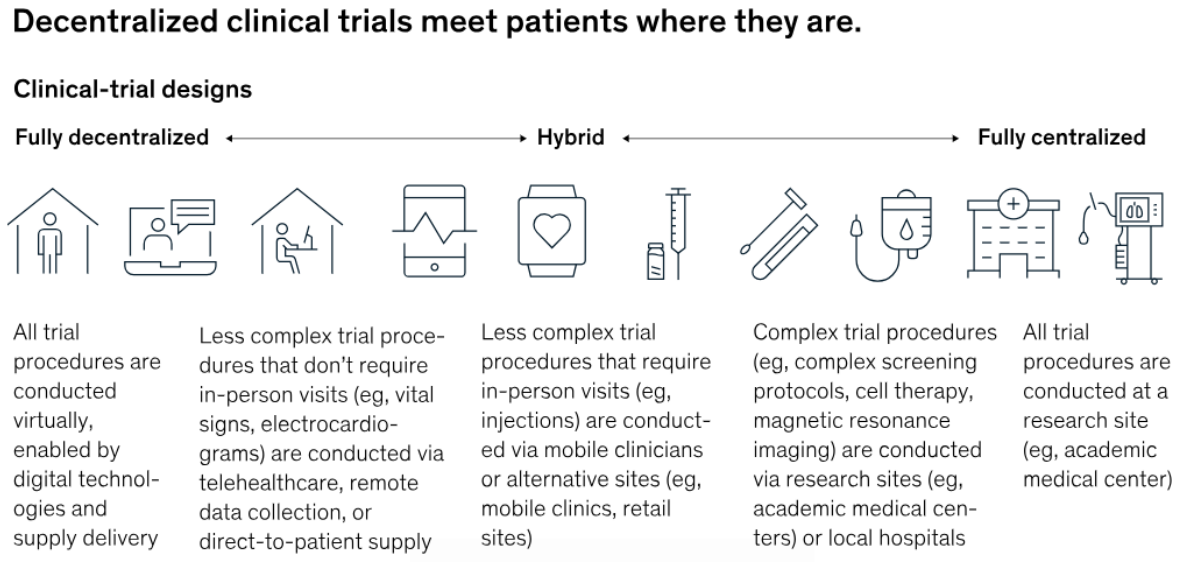



*Figure 2.8-1 clinical trial Designs (Mckinsey, 2021)*

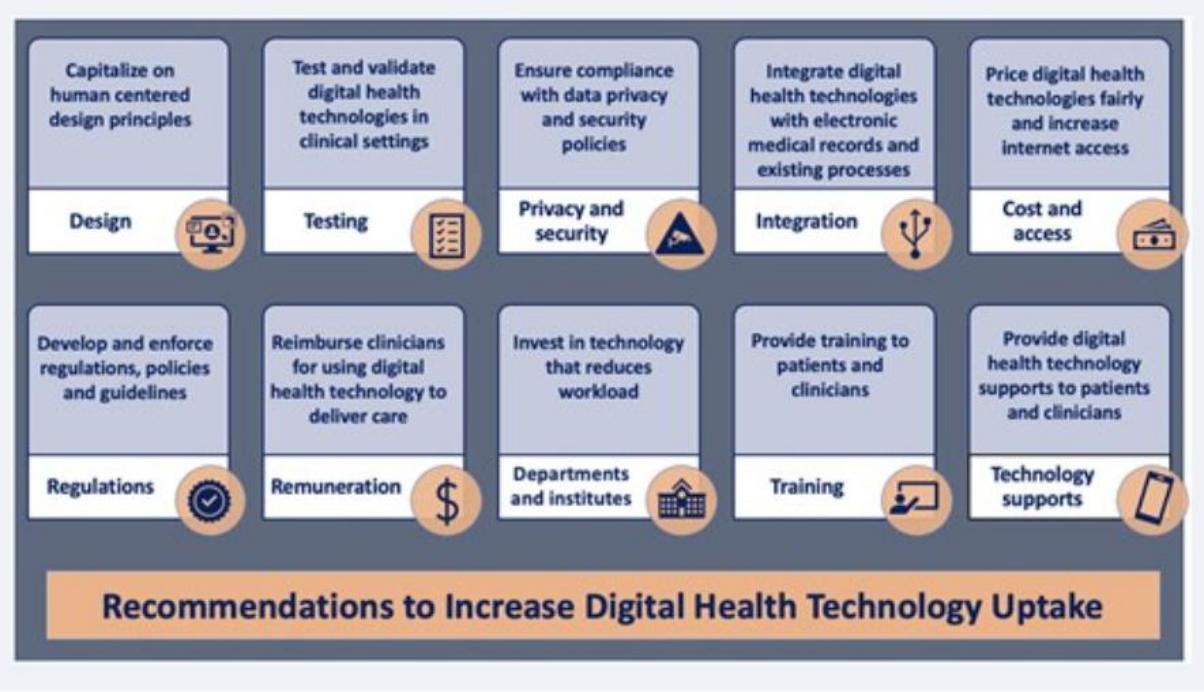



*Figure 2.8-2Recommendations to increase DHT adoption (Whitelaw et al., 2021)*

## 2.9 Gap Analysis

Despite increasing scholarly and industry attention on the role of digital health technologies (DHTs) in modernizing clinical trials, several critical research gaps remain, particularly in the context of decentralized clinical trials (DCTs). Existing literature has largely concentrated on high-income countries, leaving the adoption and implementation of DHTs in low- and middle-income countries (LMICs), such as India, underexplored. In these regions, unique challenges—such as uneven digital infrastructure, lower health system digitization, and digital literacy gaps—require localized investigation. Therefore, there is a need for empirical studies that reflect the realities of DHT deployment in LMICs.

Additionally, current research is predominantly centered on the United States and Western European nations. Comparative studies involving countries like Ireland and India remain limited, despite both having active clinical trial sectors and contrasting regulatory, economic, and digital health environments. Such comparisons can offer insights into how different health systems adapt to DCTs and the role of policy, infrastructure, and cultural acceptance in influencing adoption.

The role of Contract Research Organizations (CROs) in enabling the adoption of DHTs in DCTs also remains underexplored. CROs often act as intermediaries between sponsors, regulators, and clinical trial sites, and are instrumental in operationalizing decentralized trial models. However, academic literature has yet to sufficiently address how CROs contribute to or face challenges in supporting the digital transition, particularly in cross-national contexts.

Furthermore, existing studies have paid limited attention to patient-centric outcomes—specifically, how DHTs influence participant recruitment, retention, and engagement. These factors are critical to the success of DCTs, yet they remain insufficiently examined in current research.

Lastly, there is a need for studies that analyse how the interplay between regulatory frameworks, infrastructure quality, and population digital literacy affects the success of decentralized trials. While some works examine these elements in isolation, few adopt a comparative approach that considers them holistically across different regions.

This study seeks to address these gaps by offering a comparative analysis of Ireland and India—two countries with differing levels of digital health maturity—while examining regulatory structures, technological infrastructure, stakeholder roles (including CROs), and participant experiences with DHTs in clinical trials.

## 2.10 CONCLUSION

The shift towards decentralized clinical trials, enabled by Digital Health Technologies, offers significant opportunities to enhance trial efficiency, patient engagement, and data quality. However, challenges related to regulatory complexity, data privacy, and infrastructure limitations must be addressed to fully realize the potential of DCTs. A comparative analysis of India and Ireland highlights the importance of regulatory harmonization, infrastructure development, and CRO-led innovation in facilitating the adoption of DHTs in DCTs. Future research should focus on addressing the identified gaps and providing actionable recommendations for stakeholders.

# 3 RESEARCH METHODOLOGY

## 3.1 INTRODUCTION

This chapter explains the research methodology adopted for this study. The aim was to design a structured and systematic approach that would generate valid and reliable findings, contributing to a deeper understanding of the opportunities and challenges involved in adopting Digital Health Technologies (DHTs) in clinical trials across different regulatory environments.

The methodology mainly follows the Research Onion framework (Figure 19 ) developed by Saunders et al. (2019), which provides a clear and practical guide for designing a robust research plan. According to Saunders, research methodology refers to the overall plan that a researcher uses to answer the research questions and achieve the study's objectives. The Research Onion illustrates six layers that researchers must work through, from the outer layers to the inner ones, with each layer representing a different stage of the research process(Saunders *et al.*, 2019; Alharahsheh and Pius, 2020).

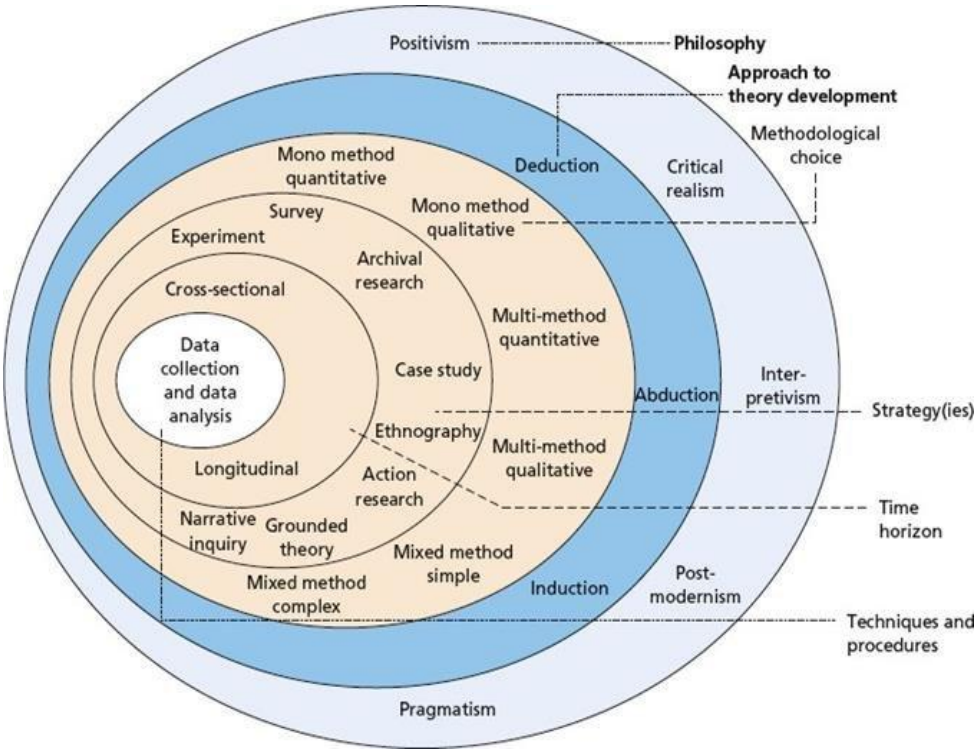



*Figure 3.1-1 Research Onion Framework(Saunders* et al.*, 2019)*

Following this structure, the methodological choices made in this study are explained and justified across six stages. First, the chapter discusses the research philosophy and the research approach to theory development. These initial decisions directly influence the next three layers: the methodological choice, the research strategy, and the time horizon. Saunders et al. (2019) note that these layers focus primarily on designing the research process — that is, how the research question is translated into practical research work.

At the final, inner layer of the onion, the chapter outlines the data collection methods and data analysis techniques employed. It also describes the sampling method and population targeted, followed by a discussion of ethical considerations, highlighting the measures taken to ensure the quality, credibility, and trustworthiness of the results.

Finally, the chapter identifies the limitations and challenges encountered during the research process and concludes with a summary of the overall research methodology.

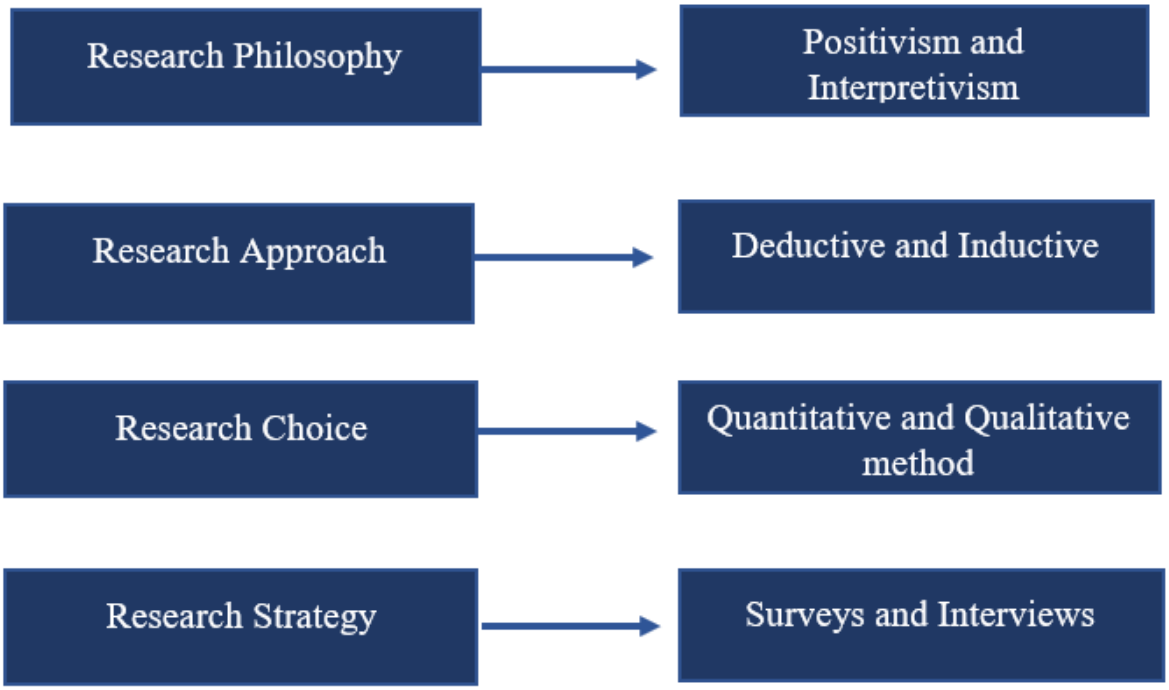



*Figure 3.1-2 Overview of Research Process (created by author)*

## 3.2 Research Philosophy

Research philosophy refers to the set of beliefs and assumptions about the development of knowledge and how it should be studied. It shapes the researcher's view of the world and the

strategies adopted to answer research questions. The researcher must critically examine their own beliefs and assumptions to choose a suitable research philosophy that aligns with research aim.

Before deciding on data collection methods, a researcher must choose a philosophical stance, known as a paradigm. A research paradigm represents a model of thinking that guides how research is conceptualized. It consists of four key elements: epistemology, ontology, methodology, and axiology(Kivunja and Kuyini, 2017; Kaushik and Walsh, 2019).

Epistemology concerns the nature and sources of knowledge, guiding how researchers decide what is considered valid (Rehman and Alharthi, 2016; Abu-Alhaija, 2019). Ontology deals with the nature of reality, whether it is viewed as objective or subjective (Kivunja and Kuyini, 2017).Methodology refers to the systematic approach used to collect and analyse data. Axiology considers the role of values and ethics in research and their influence on the findings ((Rehman and Alharthi, 2016).

Together, these elements — epistemology, ontology, methodology, and axiology — underpin the philosophical orientation of a study and directly shape the research design. Saunders et al. describe several important research philosophies:

- **Positivism** emphasizes objective, empirical study to uncover universal truths through systematic observation, measurement, and analysis. It prioritizes observable facts and scientific principles over assumptions, focusing on pure data rather than human bias (Alharahsheh & Pius, 2020). Positivism is often linked with quantitative methods like surveys, experiments, and statistical analysis to ensure objectivity**.**
- **Interpretivism** emphasizes the subjective reality. It is the best approach for research design if the research problem needs a deeper understanding, and available knowledge is limited and it is often linked with qualitative methods like interviews.
- **Critical Realism** acknowledges that while reality exists independently, it can only be understood imperfectly through human perception. It bridges positivist and interpretivist views, often using mixed methods to explore deeper structures that shape observable events.
- **Pragmatism** holds that the research question determines the methods used. Pragmatists are not committed to any one philosophical stance and often use both qualitative and quantitative techniques to find practical solutions.

- **Postmodernism** challenges the idea of a single reality or truth, emphasizing the fragmented, subjective, and constructed nature of knowledge(Saunders *et al.*, 2019).

**Justification for Chosen Philosophy**

The research topic focuses on exploring the opportunities and challenges of adopting Digital Health Technologies (DHTs) in Decentralized Clinical Trials (DCTs) across two different regulatory environments: India and Ireland. Based on the literature reviewed, existing scientific studies provided valuable data on adoption rates and technological advancements. However, they often lacked detailed insights into the experiences and practical challenges faced by stakeholders directly involved in clinical trials. This gap led to the decision to adopt a combination of positivism and interpretivism to meet the research objectives effectively.

The positivist philosophy supports the quantitative component, using structured survey questionnaires to gather measurable data on DHT usage, adoption levels, and perceived barriers. This approach allowed the identification of patterns and trends that are statistically valid and broadly applicable.

Meanwhile, interpretivism guided the qualitative component through semi-structured interviews with clinical research professionals. This approach captured rich, contextual insights into how individuals experience and respond to DHTs in their specific regulatory and cultural environments.

In summary, combining positivism and interpretivism allowed the study to balance objective measurement with subjective understanding, enabling a well-rounded exploration of DHT implementation in DCTs.

## 3.3 RESEARCH APPROACH

The research approach is the second layer of the research onion. It describes how theory and data interact in a study. Saunders et.al defined three main approaches;

- Deductive approach starts with the formulation of a general theory or hypothesis, often based on existing knowledge or literature, which is then tested through empirical data collection. It is often associated with positivism. In this approach, data is collected

through structured methods such as surveys, experiments, or observations(Zalaghi and Khazaei, 2016).

- Inductive approach involves the formulation of theories or insights from specific observations and data. It involves moving from particular cases or instances to broader generalizations. It focuses on collecting and analysing specific data to uncover patterns, themes, or trends.
- Abductive approach combines both deduction and induction. It involves exploring and identifying emerging themes or patterns from the data initially collected to generate new theories or modify existing ones, which is then further tested and refined through additional data collection(Saunders *et al.*, 2019; Gamage, 2025).

| | Deduction | Induction | Abduction |
|---|---|---|---|
| **Logic** | In a deductive inference, when the premises are true, the conclusion must also be true | In an inductive inference, known premises are used to generate untested conclusions | In an abductive inference, known premises are used to generate testable conclusions |
| **Generalisability** | Generalising from the general to the specific | Generalising from the specific to the general | Generalising from the interactions between the specific and the general |
| **Use of data** | Data collection is used to evaluate propositions or hypotheses related to an existing theory | Data collection is used to explore a phenomenon, identify themes and patterns and create a conceptual framework | Data collection is used to explore a phenomenon, identify themes and patterns, locate these in a conceptual framework and test this through subsequent data collection and so forth |
| **Theory** | Theory falsification or verification | Theory generation and building | Theory generation or modification; incorporating existing theory where appropriate, to build new theory or modify existing theory |

*Figure 3.3-1Research Approaches (Saunders* et al.*, 2019)*

### Justification for Research Approach

This study employed a combination of deductive and inductive approaches to meet its research objectives. The deductive approach, aligned with the positivist paradigm, was used in the quantitative phase. It involved testing hypotheses drawn from existing literature—specifically, that Digital Health Technologies (DHTs) improve patient recruitment, retention, and data

quality in decentralized clinical trials, and that COVID-19 accelerated their adoption. These hypotheses were evaluated using survey data collected from clinical research professionals and analysed statistically to identify measurable patterns.

In contrast, the inductive approach, associated with interpretivism, guided the qualitative phase. Semi-structured interviews were used to explore individual experiences, uncovering deeper insights into the benefits of DHTs and also about the operational, cultural, affecting DHT adoption. Themes generated through thematic analysis contributed to the development of practical recommendations and new conceptual understanding.

By integrating both deductive and inductive reasoning, the study combined theory testing with theory building, offering a comprehensive view of both the measurable outcomes and contextual influences on DHT use in decentralized clinical trials

## 3.4 RESEARCH CHOICE

Research choice refers to the type of method or combination of methods used to conduct a study. It represents an essential step in designing the research process, ensuring that the data collection and analysis techniques align with the research objectives and philosophical stance(Saunders *et al.*, 2019). There are three commonly used research choices:

- **Mono-method** refers to using a single data collection technique and corresponding analysis method. This could be either quantitative, which involves collecting and analysing numerical data to form conclusions (e.g., surveys) or qualitative, which involves analysis of non-numerical data (e.g., interviews), but not both.
- **Multi-method** involves using more than one data collection technique within the same methodological tradition. For example, a researcher may use both interviews and focus groups, which are qualitative methods(Asenahabi, 2019).
- **Mixed-methods** combine both quantitative and qualitative approaches in the same study. This method allows for the integration of numerical data with narrative insights, leading to a more comprehensive understanding of the research problem.

**Justification for the Chosen Research Choice**

This study adopted a mixed-methods approach to explore the adoption of Digital Health Technologies (DHTs) in Decentralized Clinical Trials (DCTs) across India and Ireland. The quantitative component involved structured surveys to assess adoption rates, perceived benefits, and key barriers. This allowed for hypothesis testing and trend identification across a broader population, aligning with the positivist paradigm.

The qualitative component used semi-structured interviews with clinical researchers and healthcare professionals to gain in-depth insights into real-world challenges and contextual influences. Thematic analysis was applied to uncover underlying motivations and perceptions, in line with interpretivist thinking.

Combining both methods enabled data triangulation, enhancing the validity of findings (Ojebode *et al.*, 2018). This approach, commonly used in health research, provided a more holistic understanding of both measurable trends and the complex factors shaping DHT implementation in DCTs.


*Figure 3.4-1 Mixed-Method design(Asenahabi, 2019)*

## 3.5 RESEARCH STRATEGY

Research strategy outlines the overall plan for conducting research and answering the research questions (Saunders et al., 2019). It connects the philosophical assumptions and research approach to the actual methods used to collect and analyse the data. Several strategies are available:

- **Survey** research uses questionnaires or structured interviews to collect data from a large number of respondents. It is common in quantitative studies aiming for generalizable results.
- **Case Study** focuses on an in-depth understanding of a specific organization, event, or phenomenon. It can involve both qualitative and quantitative data.
- **Experiment** tests causal relationships by manipulating variables in controlled settings. While more common in natural sciences, experiments are also used in social sciences for studying interventions.
- **Ethnography** involves immersing the researcher in the environment of the participants to understand social practices and meanings.
- **Action Research** emphasizes solving practical problems in collaboration with participants while simultaneously studying the process.
- **Grounded Theory** develops theories based on data collected during the research itself, rather than testing existing theories.
- **Archival Research** analyses existing data or records (such as company reports or public databases)(Bryman, 2016; Saunders *et al.*, 2019).

The choice of strategy is influenced by the research objectives, available resources, and philosophical stance.

Among these strategies, survey research is particularly useful when the aim is to collect a large volume of data from a broad sample in a relatively short time. Surveys are commonly used in quantitative research to identify trends, opinions, and behaviours within a population by studying a representative sample (Asenahabi, 2019). The responses are often collected through structured questionnaires using closed-ended questions, and the data are statistically analysed.(Gamage, 2025)

**Justification for the Chosen Strategy: Survey and Interview**

This study employed a combined research strategy involving both surveys and semi-structured interviews, aligning with the mixed-methods approach and the dual philosophical stance of positivism and interpretivism.

The survey strategy supported the quantitative component by collecting standardized data on DHT adoption, barriers, and opportunities across India and Ireland. It enabled broad data collection efficiently, offering generalizable insights.

In contrast, semi-structured interviews were used to explore the qualitative dimensions of the study. These interviews captured stakeholder perspectives on regulatory, cultural, and operational challenges in greater depth—insights not easily captured through surveys.

Together, these strategies provided both breadth and depth. Surveys tested hypotheses and revealed trends, while interviews offered contextual understanding, enriching the overall analysis of DHT use in decentralized clinical trials.

## 3.6 TIME HORIZON

The time horizon refers to the timeframe over which research study is conducted and the period which data is collected (Saunders et al., 2019):

- **Cross-sectional** studies collect data at a single point in time or over a short, defined period. This approach provides a snapshot of the phenomenon, which is suitable for studies with time constraints like academic research projects with time and resource limitations.
- **Longitudinal** studies collect data over an extended period, allowing researchers to study changes and trends over time. These are more resource-intensive but useful for understanding development and causality.

Choosing the correct time horizon depends on the nature of the research questions and practical constraints like time and funding(Saunders *et al.*, 2019; Gamage, 2025).

**Justification for the chosen Time Horizon:**

For this study, a cross-sectional time horizon was selected. The primary reason for choosing a cross-sectional time horizon is the time constraint associated with completing the dissertation. The study was designed to be conducted within a three-month period, from February to May 2025, making a longitudinal design impractical. Despite its limited timeframe, the cross-

sectional approach helped to meet the research objectives by enabling the collection of current data on the adoption, effectiveness, and challenges of Digital Health Technologies in DCTs across India and Ireland.

## 3.7 DATA COLLECTION AND ANALYSIS

This is the sixth and last layer of the Saunders research onion. The process used at this stage of the research contributed significantly to the study's overall reliability and validity. This layer explains how the data is collected and analysed. It also explains the source of the data, the sample, the sample size, and ethical considerations. The data collected could include both primary and secondary data. Primary data is the data collected from the source or first hand, whereas the secondary data is the data derived from the work or opinions of other researchers. (Saunders *et al.*, 2019(Thesismind, 2019)

### 3.7.1 Study Sample and Population

**Target Population**

The target population for this study includes clinical research professionals actively involved in decentralized clinical trials (DCTs) in India and Ireland. This population encompasses individuals working in roles such as Clinical Research Coordinators (CRCs), Clinical Trial Managers (CTMs), Clinical Research Associates (CRAs), Clinical Data Managers, Principal Investigators, and other relevant stakeholders. These individuals were selected based on their direct involvement in clinical trials and their familiarity with digital health technologies (DHTs), making them well-suited to provide insights into DHT implementation. The study population also included Research Nurses to gather insights into patient perspective towards the adoption of DHTs in clinical trials.

**Sample Size Determination**

Sample size represents the number of respondents selected from the overall population that are used in the research. It affects the reliability and generalizability of the results, especially in the case of quantitative studies (Andrade, 2020).

According to the Clinical Trial Registry India (CTRI), a total of 54,547 clinical trials are currently registered and ongoing in India (Adepwar, 2023). In contrast, a report by the Irish Pharmaceutical Healthcare Association (IPHA) indicates that only 460 clinical trials were conducted in Ireland over a ten-year period from 2014 to 2023 (IPHA, 2024). However, no single, up-to-date official figure exists for the total number of clinical research professionals in either country, which posed a challenge in determining an accurate population size.

To address this, the sample size was estimated using an online sample size calculator (calculator.net). A confidence level of 90% and a margin of error of 7% were selected to strike a balance between statistical reliability and the practical constraints of time and available resources.

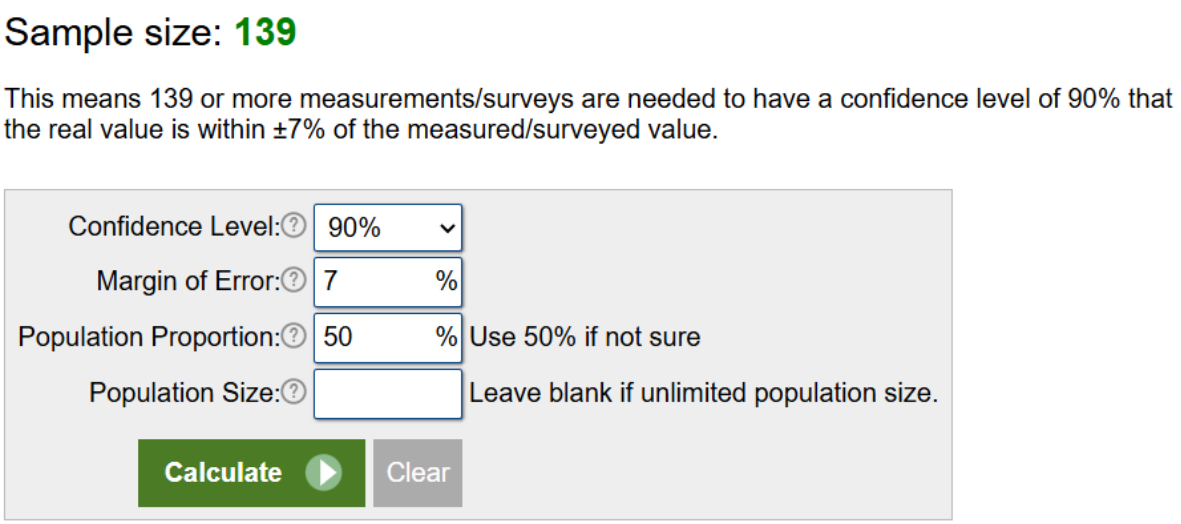



*Figure 3.7-1 Sample size(Calculator.net, 2025)*

These sample sizes provide a basis for drawing reliable conclusions and comparing adoption patterns across both countries.

**Sampling Method and Technique**

This study employed a non-probability purposive sampling method for both quantitative and qualitative components. Purposive sampling is a technique where participants are deliberately selected based on specific characteristics that align with the research objectives. Unlike random sampling, where each member of the population has an equal chance of selection, purposive

sample involves identifying and targeting individuals who are more likely to provide rich and reliable information about the research topic(Campbell *et al.*, 2020).

The participants were selected based on specific inclusion criteria, particularly having a minimum of three years of experience in clinical research for survey participation. This approach ensured that all respondents possessed sufficient exposure to DHTs and decentralized trial processes.

For the qualitative interviews, purposive sampling was also used, focusing on senior professionals with at least 5 years of experience in clinical trials. This subset was selected to gain deeper, expert-level insights into the strategic, operational, and regulatory challenges associated with DHT adoption.

**Participant Recruitment**

Participants were recruited through professional networks, direct LinkedIn outreach, email invitations, and also through snowball sampling method where initial participants were asked to refer others within their network who met the inclusion criteria.

### 3.7.2 Primary Data Collection:

**Quantitative Data Collection- Survey (Refer Appendix 1)**

The survey will be conducted using Google Forms, and participants will be asked to complete the survey in approximately 5- 7 minutes**.** The survey will consist of closed-ended questions like Likert type and multiple-choice questions and also open-ended questions designed to assess the frequency of use, perceived effectiveness, and attitudes toward digital tools in clinical trials. These questions will cover aspects such as:

- The types of digital tools used in clinical trials
- The perceived effectiveness of these tools in patient recruitment and engagement
- Barriers to the adoption of digital technologies in clinical trials
- Future of Clinical Trials

**Qualitative Data Collection**

The interviews will be conducted via Zoom with clinical research professionals from India and Ireland who have more than 3 years of experience in the field. The interviews will be semi-structured, with open-ended questions designed to capture in-depth insights into the participants' experiences with digital health tools. Topics will include:

- The types of digital tools used in clinical trials
- Challenges encountered when introducing digital tools in trials
- Perspectives on the role of Contract Research Organization(CROs) in the adoption of digital tools
- Recommendations for improving the integration of digital tools in clinical trials

### 3.7.3 Secondary Data Collection

The secondary research component of this study involved a detailed review of relevant academic and industry-based literature to support the primary findings and provide theoretical context. Key sources included peer-reviewed scientific journals, academic books, regulatory guidelines, and credible websites related to the implementation of Digital Health Technologies (DHTs) in Decentralized Clinical Trials (DCTs).

A focused search was conducted using scholarly databases such as PubMed, ScienceDirect, SpringerLink, and Google Scholar to access recent studies on DHT adoption, challenges in decentralized clinical trials, and comparative insights between different healthcare systems. In addition, official regulatory sources such as the European Commission (EU), World Health Organisation (WHO) websites were reviewed to understand compliance frameworks and digital trial governance guidelines applicable to India and Ireland.

Industry reports and content from clinical research organizations (CROs), technology solution providers, and healthcare innovation portals were also included to gain practical insights into the evolving landscape of DHT tools such as eConsent platforms, remote monitoring systems, and telemedicine interfaces.

These secondary sources were critically assessed for reliability, relevance, and credibility. The information gathered contributed to shaping the research framework, informed the survey and interview design, and supported the interpretation of findings. The review of secondary

literature ensured that the study was grounded in current best practices and aligned with international research trends.

### 3.7.4 Data Analysis

The data analysis can be divided based on research methods.

• **Thematic analysis**: For the Qualitative method, the data analysis was through thematic analysis.

• **Likert Scale Analysis**: For the Quantitative method, the data analysis was done through Likert scale analysis

**Quantitative method**

Quantitative data for this study was collected through an online survey targeting clinical research professionals in India and Ireland. The responses included a mix of Likert scale questions, multiple-choice questions (MCQs), and yes/no questions, allowing for both descriptive and inferential statistical analysis.

Once the data was collected, it was cleaned, coded, and imported into Microsoft Excel and Minitab for analysis. Descriptive statistics, including frequencies, percentages, and means, were used to summarize key variables such as the frequency of DHT usage, perceived effectiveness, and commonly encountered barriers. Cross-tabulations were applied to compare results between India and Ireland across several variables.

The Likert Scale analysis technique allows the evaluation of opinions, behaviour, attitudes, and perceptions of individuals using a structured rating system (Bhandari, 2020). It consists of a question or statement followed by five or seven response points, with the two extremes serving as response anchors-clearly indicating strong agreement or disagreement. The midpoint option usually represents a neutral or undecided response.

The five-point Likert scale format used in this study is as follows:

2. Strongly agree
3. Agree

4. Neutral
5. Disagree
6. Strongly Disagree

Bar charts and pie charts will be used to represent the study results

This approach allowed for the identification of patterns and relationships within the data, supporting hypothesis testing and comparisons across demographic subgroups, including years of experience and role type.

**Qualitative method:**

The qualitative data gathered from interviews were processed through a structured three-phase approach: transcription, coding, and thematic analysis(Braun and Clarke, 2006).

Transcription was the initial step, where Zoom interview recordings were transcribed using the captions feature. These were converted into Word documents, with the interviewer labeled as "I" and the participant as "R" for clarity.

In the coding phase, Microsoft Excel was used to manage and organize the data. Each interview was assigned a unique identifier (e.g. For India as PIN1 and for Ireland as PIR1 ), and responses were categorized by interview questions (labeled as IQ) and corresponding participant replies (R). Coding helped identify recurring patterns and relationships across the interviews.

Next, thematic analysis was conducted. Key ideas and frequently mentioned insights were grouped into overarching themes that reflected participants' shared experiences. Each theme was linked to reference numbers for traceability and organization.

For the final stage, the most relevant themes were selected and compared against secondary data from literature. This cross-analysis enabled deeper interpretation and helped address the research objectives and questions effectively.(Naeem *et al.*, 2023)

## 3.8 ETHICAL CONSIDERATIONS

Ethical considerations form a fundamental part of any research involving human participants, ensuring that the study is conducted with integrity, transparency, and respect for individuals.

According to Saunders et al., research ethics refers to the moral principles and standards that guide behaviour in the design, conduct, and reporting of research, helping to prevent malpractice and protect the rights of all participants.

This study involves a mixed-methods approach and includes both survey participants and interviewees from India and Ireland. As such, all ethical standards outlined in the relevant codes of conduct and data protection legislation (such as EU GDPR 2016/679**)** were followed carefully. Ethical approval was obtained prior to the commencement of the study, and the research adhered to the general principles of ethical conduct: research merit and integrity, respect for persons, beneficence, non-maleficence, and justice (Figure 23) (Alele and Malau-Aduli, 2023)

**Research Merit and Integrity**

The research aimed to contribute meaningfully to the field of Digital Health Technologies (DHTs) in decentralized clinical trials. Methods were designed for rigour and transparency, and all procedures—data collection, analysis, and reporting—were conducted responsibly with no tolerance for plagiarism or data manipulation.

**Informed Consent and Respect for Persons**

Participants' rights and autonomy were respected throughout. Survey participants were informed of the voluntary nature of the study, with explicit consent obtained at the beginning of the questionnaire. Interviewees received detailed information sheets and consent forms, which they signed before participation. They were reminded of their right to withdraw at any time.

**Data Privacy and Confidentiality**

Survey responses were anonymous with no identifiable information collected. Interview data was stored on a secure, password-protected device and anonymized using participant codes (e.g., PIN1, PIR2). Data will be securely retained for at least two years in line with ethical guidelines.

**Minimization of Harm and Beneficence**

Participants were not exposed to any form of harm. Questions in both the survey and interviews were respectful and non-intrusive. The study aims to benefit the clinical research community by informing strategies to improve DHT adoption in decentralized trials.

**Justice and Fair Recruitment**

Participant selection was fair, based on relevant experience (minimum of three years for survey respondents and ten years for interviewees). No coercion was involved in recruitment. The study promoted diversity by including participants from India and Ireland across multiple professional roles.

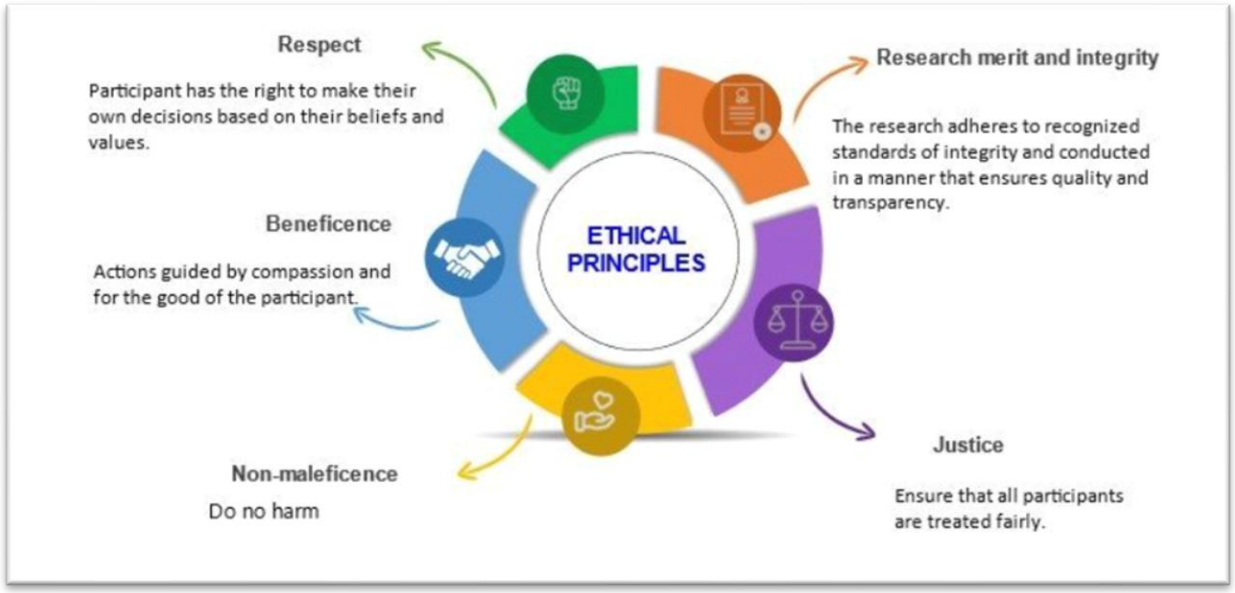
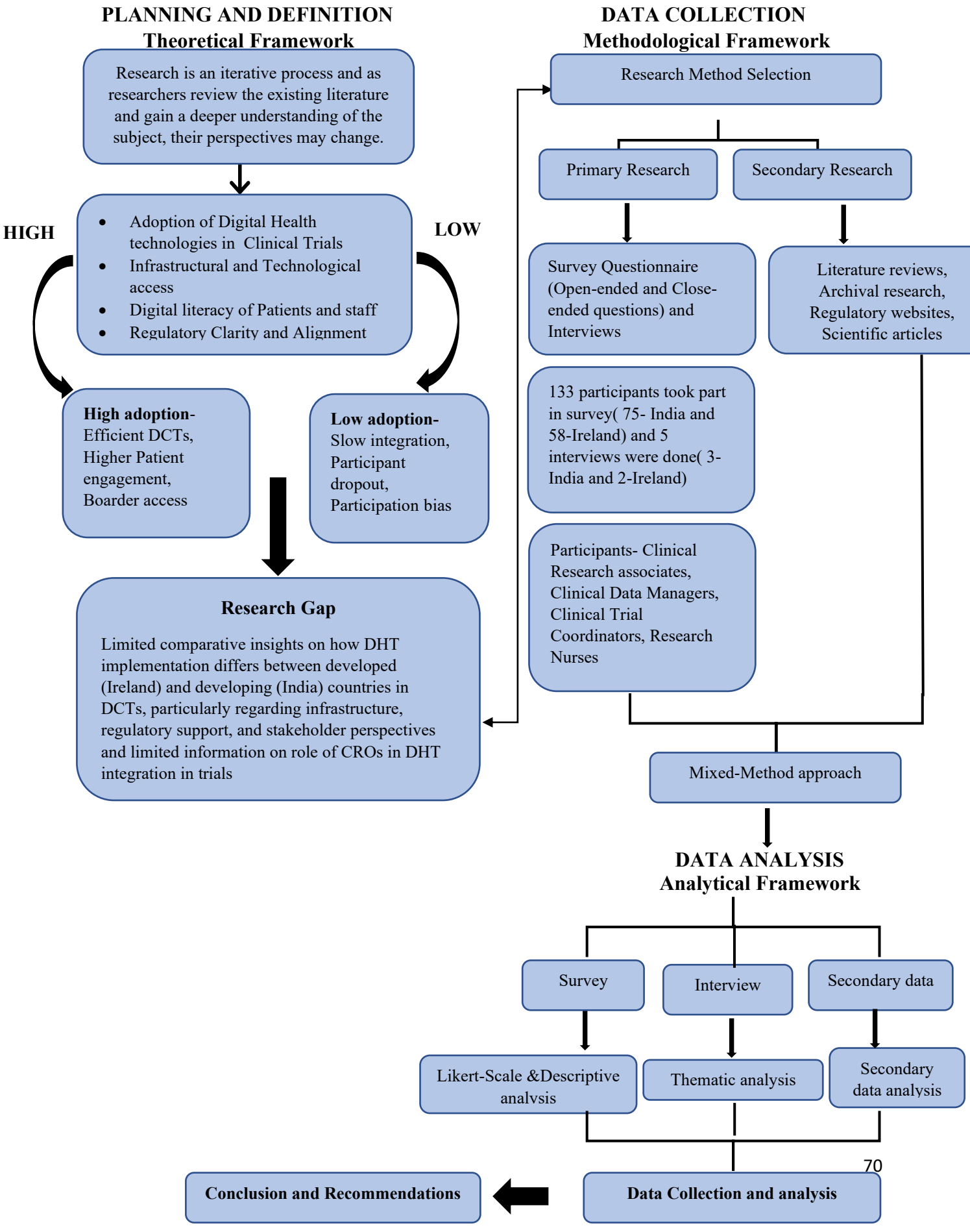



*Figure 3.8-1 Principles of Research Ethics(Alele and Malau-Aduli, 2023)*

## 3.9 CONCEPTUAL FRAMEWORK



# 4 FINDINGS AND ANALYSIS

## 4.1 OVERVIEW

This chapter presents the findings from the qualitative and quantitative data collected during the study. The responses obtained through Google Forms were systematically transferred to Microsoft Excel and Minitab for detailed analysis, and the findings from the semi-structured interviews were analysed through thematic analysis.

## 4.2 QUANTITATIVE DATA ANALYSIS

For the Quantitative Method, the surveys were conducted with the Clinical Research Professionals, like Clinical Research Associate, Clinical Trial Coordinator, Clinical Data Manager, Clinical Trial Assistants, and also healthcare providers like Clinical Research Nurse to collect data to gather insights into the benefits, challenges, and adoption rate of DHTs in Clinical Trials. A total of 134 responses were gathered from the participants.

**Participant consent**

Obtaining informed consent from participants is a fundamental aspect of ethical research. It ensures that participants are fully aware of the risks, benefits, and available alternatives before taking part in the study (Shah et al., 2024). Prior to data collection, the study clearly outlined its purpose and objectives to all participants. The researcher ensured that participation was entirely voluntary, and that participants had the right to withdraw at any stage without any obligation.

**Question 1:** To confirm participants understood the aim and scope of the study, the survey included a mandatory question requiring them to acknowledge reading the introductory statement. All 134 individuals who completed the survey confirmed that they had read and understood the study's purpose(Figure 4.2.1)

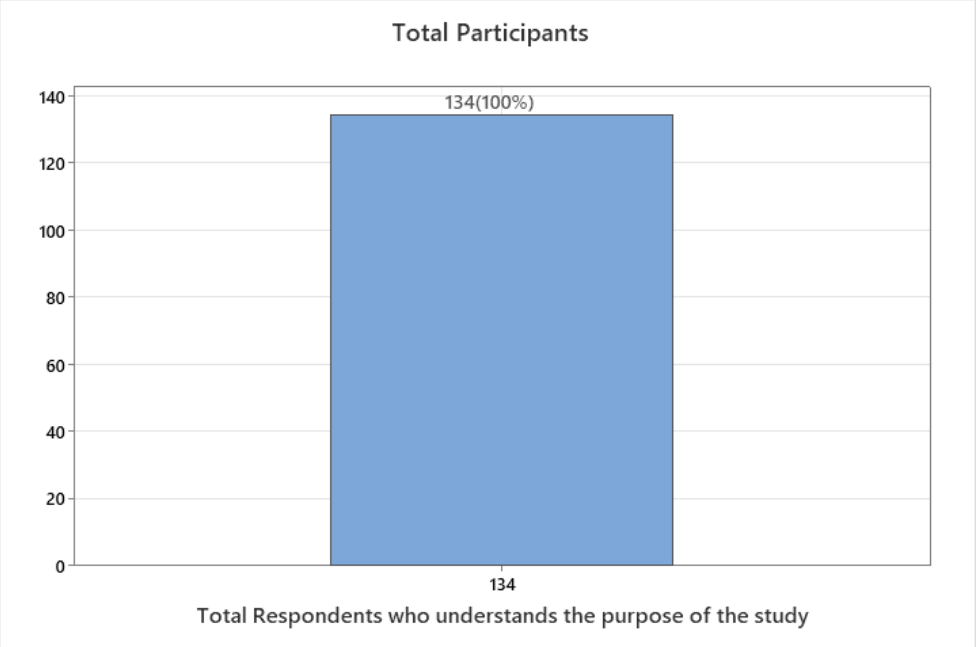



*Figure 4.2-1 Number of Participants who read and understand the purpose of the survey*

**Question 2:** Voluntary participation is an essential component of ethical research practices(Saunders *et al.*, 2019). The second mandatory question in the survey was designed to confirm that participants were choosing to take part voluntarily. Participants who chose not to continue after reading the study overview were free to opt out. Of the 134 participants, 133 (97.1%) provided voluntary consent to participate, while 1 participant (2.9%) chose to withdraw from the study.

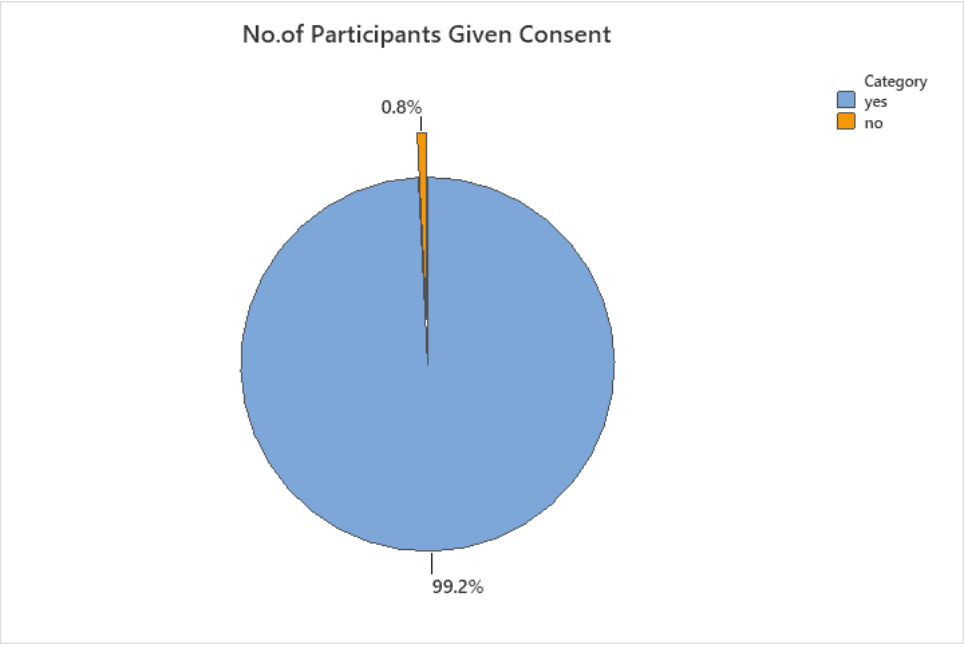



*Figure 4.2-2 Pie Chart of Number of Participants who gave consent*

## Demographics

Understanding the demographic characteristics of the participants is essential for contextualizing the findings and ensuring that the study has reached the appropriate target population (Hammer, 2011). Collecting data such as country of residence, gender, age group, level of education, and professional role helps in evaluating the diversity, relevance, and generalizability of the responses within the field of decentralized clinical trials (DCTs) and digital health technologies (DHTs).

### Country of Residence

Out of the total 133 respondents, 75 (56.4%) were from India, while 58 (43.6%) were from Ireland. This distribution indicates a strong representation from both countries, aligning with the comparative nature of this study. The overrepresentation of Indian professionals reflects the higher outreach and availability of clinical research professionals in India.

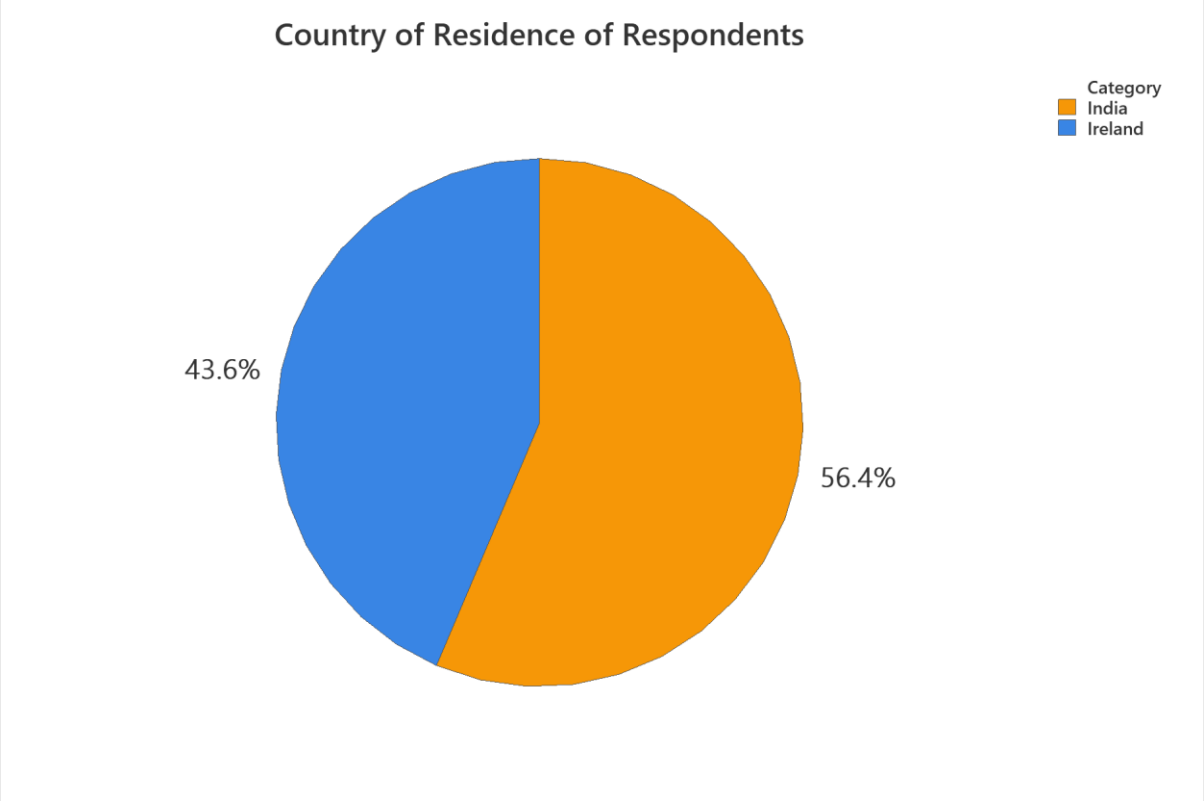



*Figure 4.2-3 Country of Residence of Respondents*

### Gender Distribution

Out of 133 clinical research professionals surveyed, 64.7% were female and 35.3% were male. Female respondents were the majority in both countries, with 50 from India and 36 from Ireland. This gender distribution highlights the prominent role of women in the clinical research workforce across both regions

*Table 4.2-1 Gender Distribution of Respondents*

| Country | Gender | | Total |
|---|---|---|---|
| | Male | Female | |
| **India** | 25 (18.8%) | 50 (37.5%) | 75 (56.3%) |
| **Ireland** | 22 (16.6%) | 36(27.1%) | 58 (43.7%) |
| **Total** | 47 (35.3%) | 86 (64.7%) | 133 (100%) |

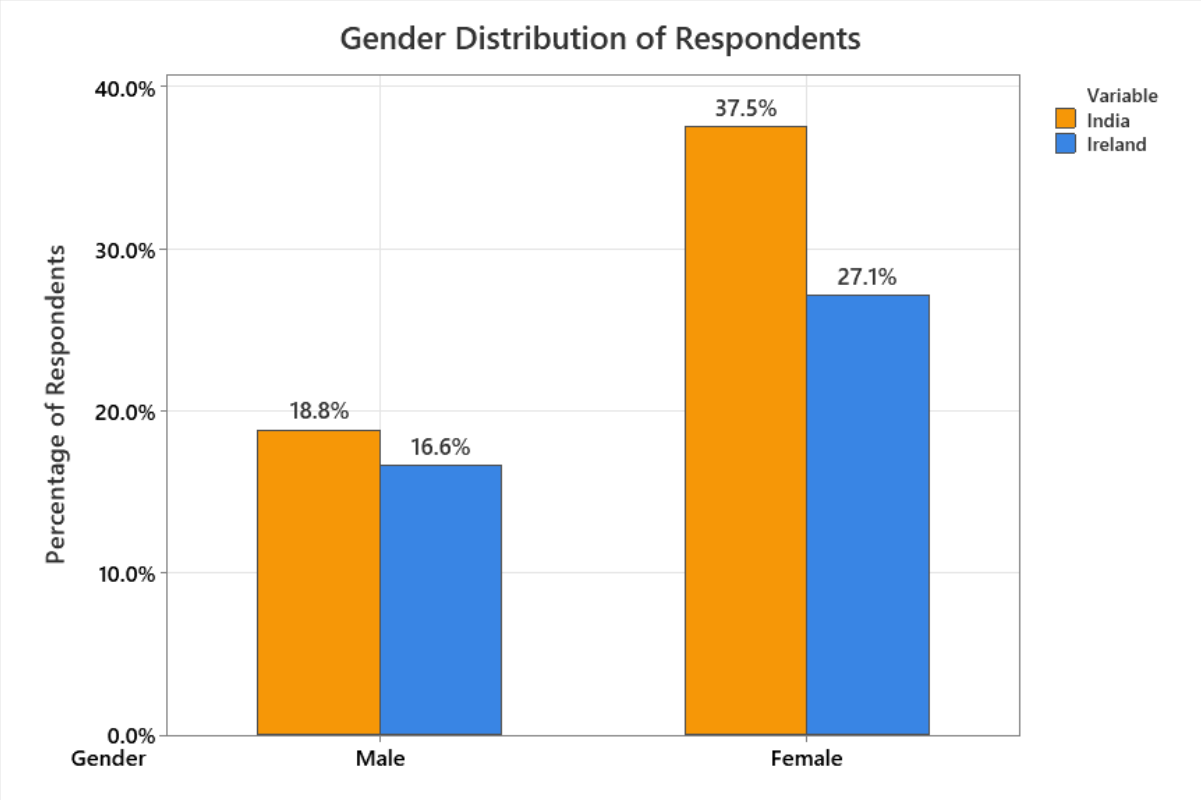



*Figure 4.2-4 Clustered Column Chart of Gender Distribution of Respondents*

### Age Group of Respondents

The majority of respondents (63.1%) were aged between 25–35 years, with 51 from India and 33 from Ireland, indicating a strong representation of early-career professionals. This was followed by the 18–25 age group (30.8%), comprising 22 Indian and 19 Irish participants. Only a small proportion were aged 35–45 (4.5%) and 45–55 (1.5%). Overall, the data shows that the study predominantly involved younger clinical research professionals, who may be more receptive to adopting digital health technologies.

*Table 4.2-2 Age group of Respondents*

| Age Group | Country | | Total |
|---|---|---|---|
| | India | Ireland | |
| **18-25** | 22 (16.5%) | 19(14.3%) | 41(30.8%) |
| **25-35** | 51(38.3%) | 33(24.8%) | 84(63.1%) |
| **35-45** | 1(0.75%) | 5(3.75%) | 6(4.5%) |
| **45-55** | 1(0.75%) | 1(0.75%) | 2(1.5%) |
| **Total** | 75(56.4%) | 58(43.6%) | 133(100%) |

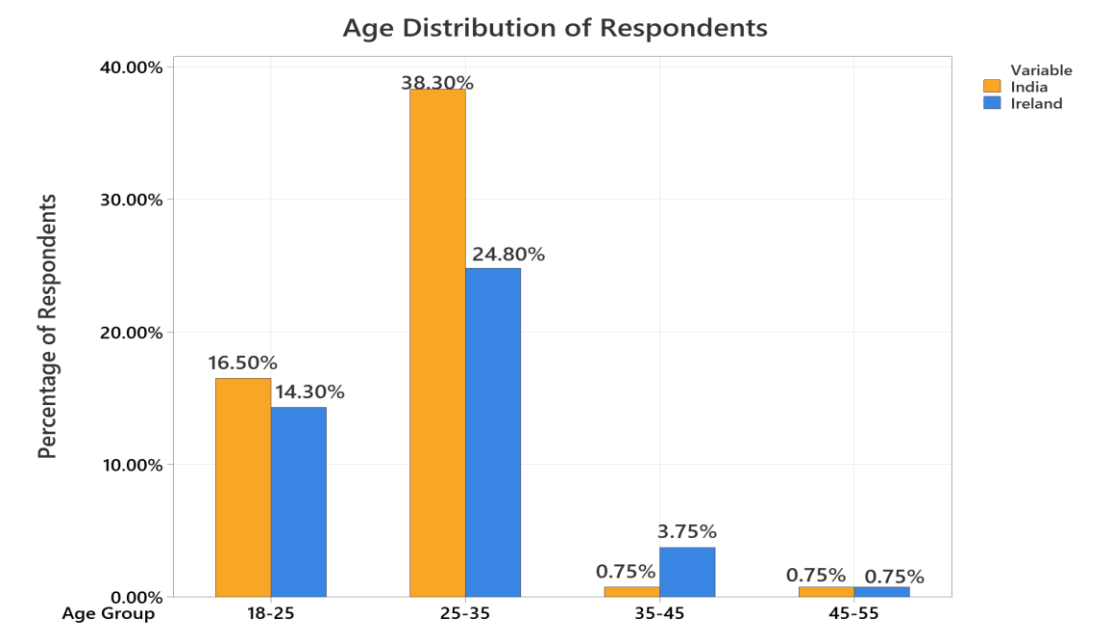



*Figure 4.2-5 Clustered Column Chart of Age Distribution of Participants*

**Educational Qualification**

The survey of 133 professionals revealed that 47.4% (n=63) held Master's degrees, evenly distributed between India (21.8%, n=29) and Ireland (25.6%, n=34). Bachelor's degrees were the second most common (37.6%, n=50), with more Indian respondents (24.8%, n=33) than Irish (12.8%, n=17). Only 12.0% (n=16) had Doctorates (India: 8.3%, n=11; Ireland: 3.7%, n=5), while a small minority (1.5%, n=2) held diplomas. The findings indicate a high proportion of postgraduate-educated professionals working with DHTs in DCTs across both regions, suggesting strong academic readiness for digital trial implementation

*Table 4.2-3 Educational qualification of respondents*

| Educational Qualification | Country | | Total |
|---|---|---|---|
| | India | Ireland | |
| **Doctorate** | 11(8.3%) | 5(3.7%) | 16(12.0%) |
| **Master's Degree** | 29(21.8%) | 34(25.6%) | 63(47.4%) |
| **Bachelor's degree** | 33(24.8%) | 17(12.8%) | 50(37.6%) |
| **Advance Diploma** | 1(0.75%) | 1(0.75%) | 2(1.5%) |
| **Certificate/Diploma** | 1(0.75%) | 1(0.75%) | 2(1.5%) |
| **Total** | 75(56.4%) | 58(43.6%) | 133(100%) |

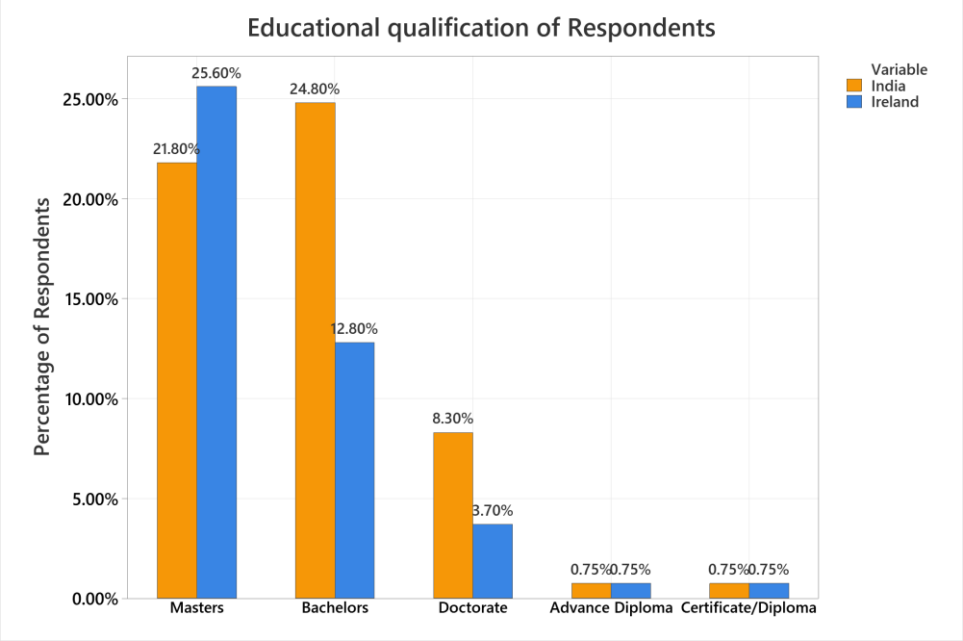



*Figure 4.2-6 Clustered Chart showing Educational qualification of Respondents*

**Current Role of Respondents**

The study surveyed professionals across diverse roles in India and Ireland. Clinical Research Associates were most common (37.6%, n=50), followed by Clinical Trial Coordinators (18.8%) and Clinical Data Managers (13.6%). Research Nurses represented 12% of respondents, while Clinical Trial Assistants (8.3%) were exclusively from India. Senior/specialized roles (e.g., Trial Managers, PIs) and other positions (e.g., Data Coordinators) were less frequent.

*Table 4.2-4 Role of Respondents*

| Current Role | Country | | Total |
|---|---|---|---|
| | India | Ireland | |
| **Clinical Research Associate** | 24(18.1%) | 26(19.5%) | 50(37.6%) |
| **Clinical Trial Assistant** | 11(8.3%) | 0 | 11(8.3%) |
| **Clinical Trial Coordinator** | 15(11.3%) | 10(7.5%) | 25(18.8%) |
| **Clinical Data Manager** | 9(6.8%) | 9(6.8%) | 18(13.6%) |
| **Clinical Trial Manager** | 3(2.25%) | 3(2.25%) | 6(4.5%) |
| **Clinical Document Analyst** | 1(0.75%) | 0 | 1(0.75%) |
| **Clinical Data Coordinator** | 1(0.75%) | 0 | 1(0.75%) |
| **Principle Investigator** | 1(0.75%) | 0 | 1(0.75%) |
| **Clinical Operations Manager** | 1(0.75%) | 1(0.75%) | 2(1.5%) |
| **Advocate for Research Subjects** | 0 | 1(0.75%) | 1(0.75%) |
| **Research Nurse** | 9(6.8%) | 7(5.3%) | 16(12%) |
| **Assistant Manager** | 0 | 1(0.75%) | 1(0.75%) |
| **Total** | 75(56.4%) | 58(43.6%) | 133(100%) |

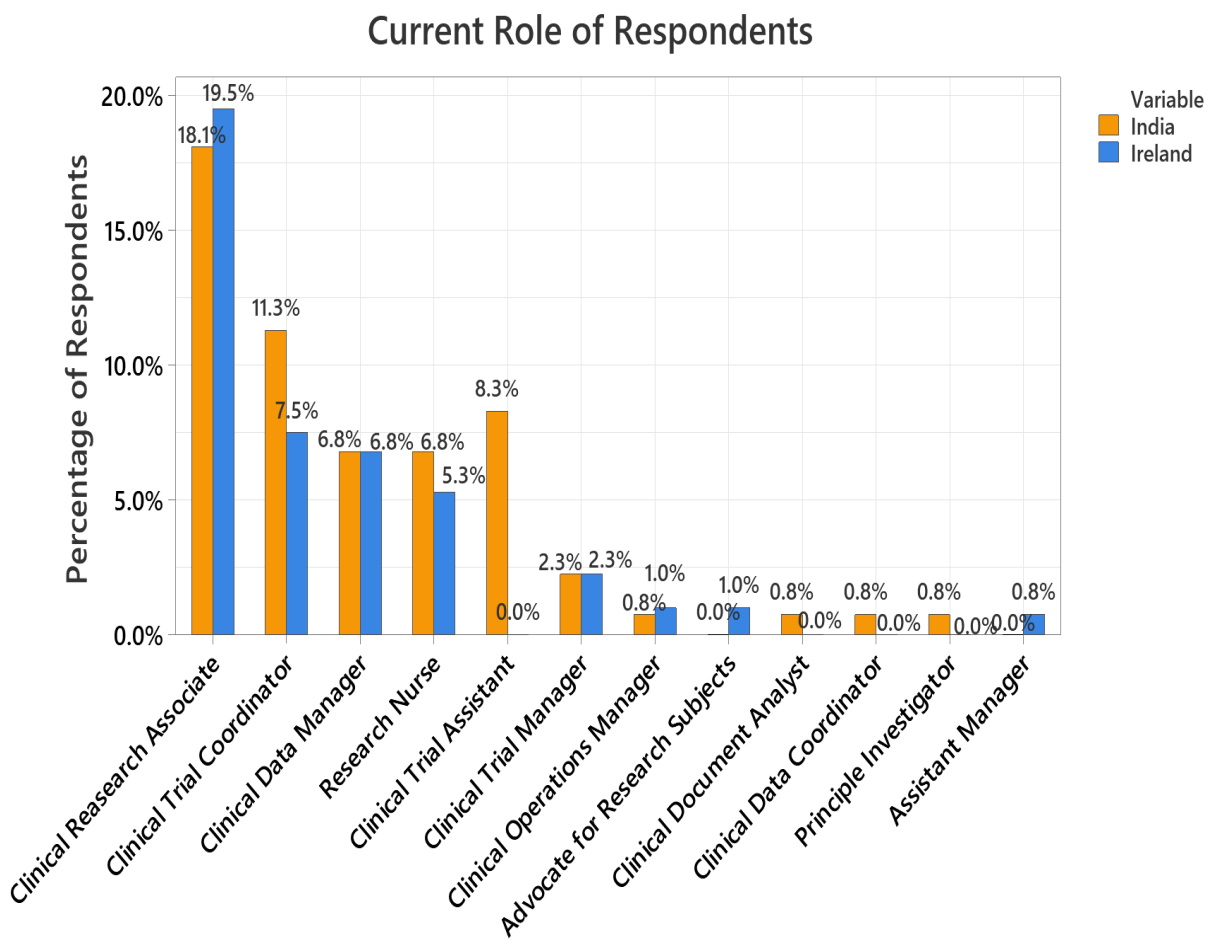



*Figure 4.2-7 Clustered Column Chart showing Current Role of Respondents*

**Experience of Respondents**

The majority of respondents (81.2%) reported having 1 to 3 years of experience in clinical trials, with 61 participants from India and 47 from Ireland. A smaller portion (14.3%) had 4 to 6 years of experience, while only 4.5% had more than 7 years in the field. No participants reported having less than 1 year of experience. This indicates that most respondents are early-career professionals actively engaged in clinical trial activities, providing relevant insights into current practices and challenges in decentralized clinical trials.

*Table 4.2-5 Years of experience of respondents*

| Years of Experience | Country | | Total |
|---|---|---|---|
| | India | Ireland | |
| Less than 1 year | 0 | 0 | 0 |
| 1-3 years | 61(45.9%) | 47(35.3%) | 108(81.2%) |
| 4-3 years | 10(7.5%) | 9(6.8%) | 19(14.3%) |
| More than 7 years | 4(3.0%) | 2(1.5%) | 6(4.5%) |
| Total | 75(56.4%) | 58(43.6%) | 133(100%) |

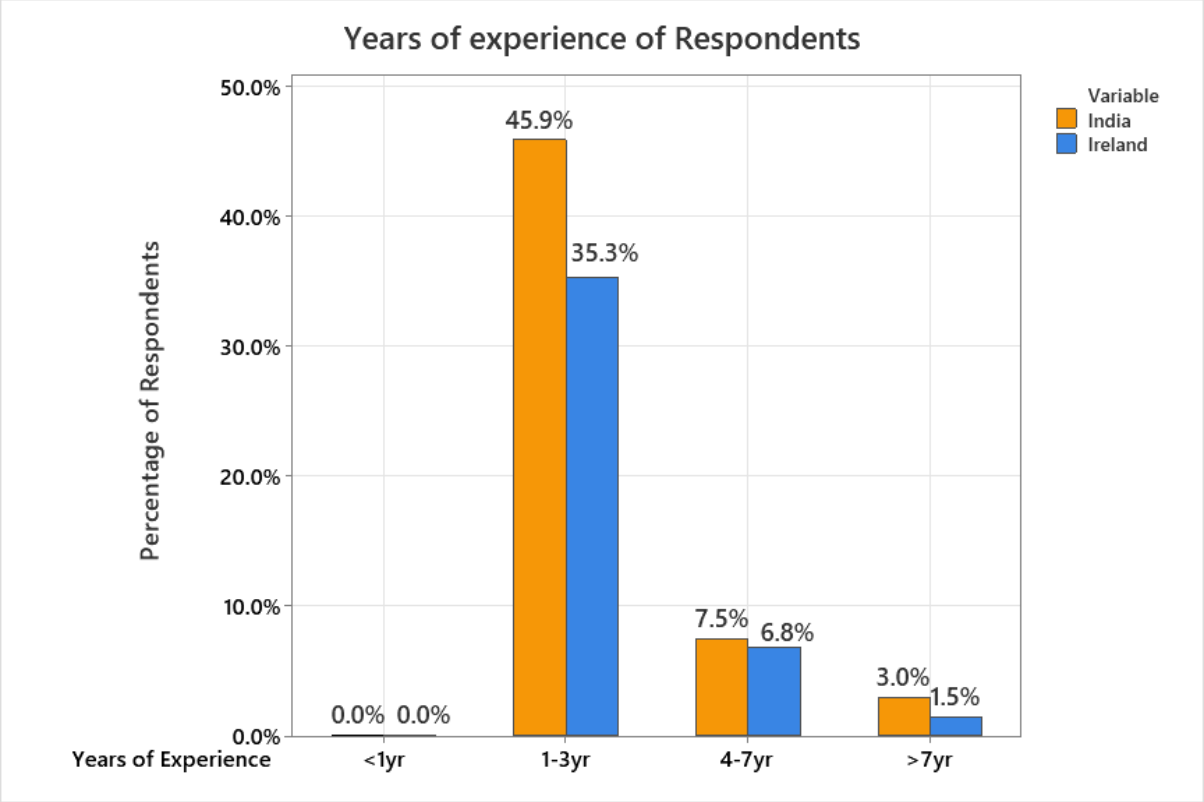



*Figure 4.2-8 Clustered chart showing Years of Experience of Respondents*

## Analysis of the objectives of the study from the survey questionnaire

### Analysis of Objective I :

To assess the current level of adoption and types of Digital Health Technologies (DHTs)—such as telemedicine, e-consent, remote monitoring, and wearable devices—used in decentralized clinical trials (DCTs) in India and Ireland.

**Questions asked to Clinical Research Professionals- Clinical Research Associate, Clinical Data Manager, Clinical Trial Coordinator, Clinical Trial Assistant**

### A) Questions asked to assess the current level of adoption

**Q1: How would you rate your organization's overall adoption of Digital Health Technologies (DHTs) in clinical trials?**

The survey data reveals distinct differences in the adoption levels of Digital Health Technologies (DHTs) between India and Ireland. In India, 30.3% of respondents reported no adoption of DHTs, while the remaining were distributed across early (28.8%), moderate (15.1%), advanced (13.6%), and fully integrated (12.2%) stages. In contrast, Ireland showed no instances of non-adoption, with higher proportions in advanced (23.5%) and fully integrated (33.2%) categories, indicating more widespread and mature DHT integration.

*Table 4.2-6 Rate of overall adoption of DHTs in Clinical Trials*

| Rate of overall adoption of DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Not adopted | 20 | 30.3% | 0 | 0% |
| Early stages of adoption | 19 | 28.8% | 11 | 21.6% |
| Moderate adoption | 10 | 15.1% | 11 | 21.6% |
| Advanced adoption | 9 | 13.6% | 12 | 23.5% |
| Fully Integrated | 8 | 12.2% | 17 | 33.2% |
| Total Respondents | 66 (100%) | | 51(100%) | |

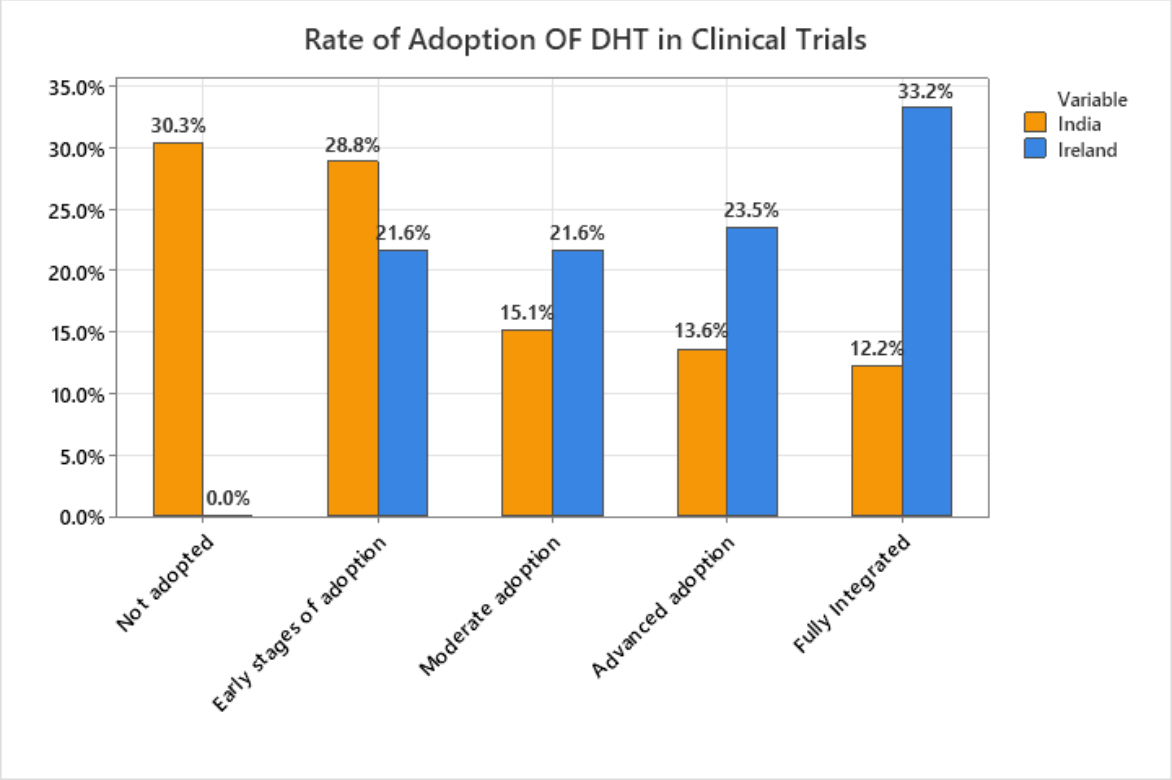



*Figure 4.2-9 Clustered Column Chart showing Rate of Adoption of DHT in Clinical Trials*

**Q2: How has the COVID-19 pandemic influenced your organization's adoption of DHTs in Clinical Trials?**

The survey data reveals distinct patterns in how COVID-19 influenced DHT adoption across both countries. In Ireland, 92.1% of respondents reported accelerated DHT adoption (52.9% significant, 39.2% moderate) due to COVID-19. India showed more varied results, with 62.1% reporting acceleration (36.4% significant, 25.7% moderate) but 30.3% indicating no change in adoption rates. Both countries reported minimal slowdowns (India: 7.6%; Ireland: 5.9%). The findings demonstrate that while COVID-19 predominantly accelerated DHT adoption in both locations(Van, 2021; FDA, 2024b), Ireland experienced more widespread and consistent acceleration compared to India's more heterogeneous response.

*Table 4.2-7 Influence of COVID-19 pandemic on adoption of DHTs in clinical trials*

| Influence of the COVID-19 Pandemic on the adoption of DHTs in clinical trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| No Change | 20 | 30.3% | 0 | 0% |
| Significantly accelerated | 24 | 36.4% | 28 | 52.9% |
| Moderately accelerated | 17 | 25.7% | 20 | 39.2% |
| Slowed adoption | 5 | 7.6% | 3 | 5.9% |
| Total Respondents | 66 (100%) | | 51(100%) | |

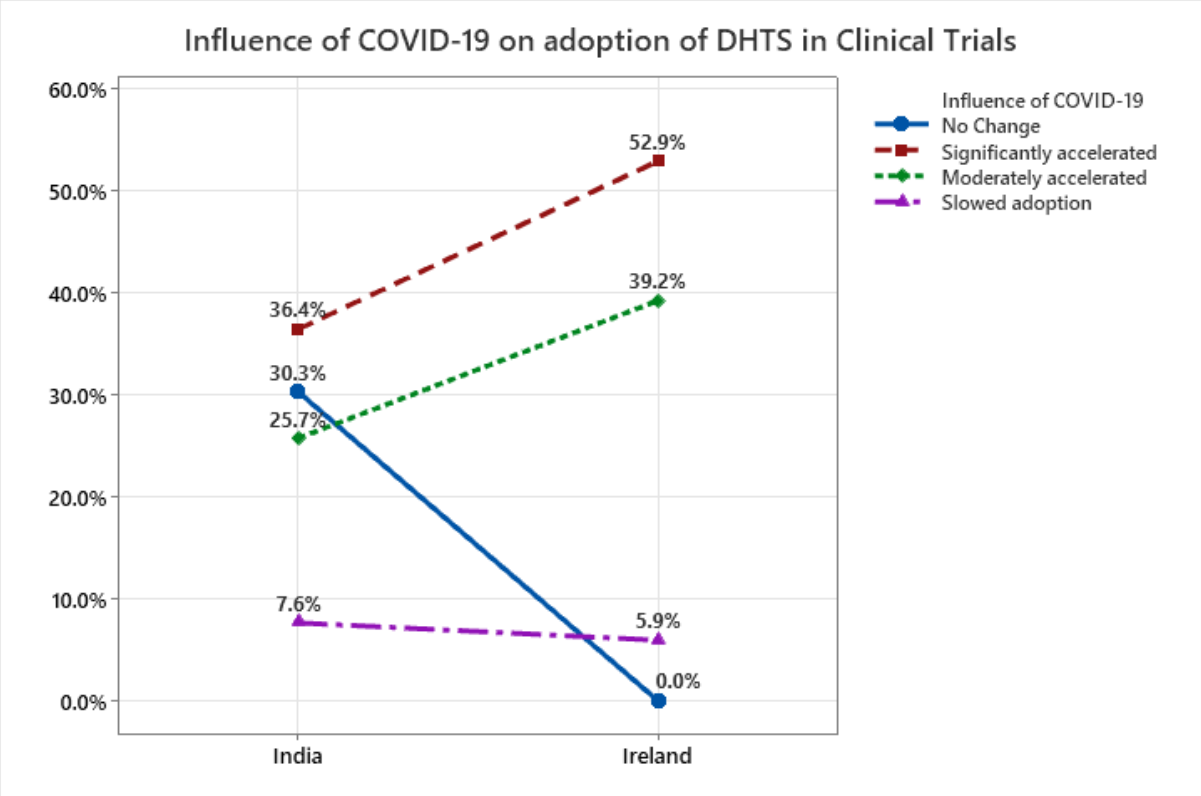



*Figure 4.2-10 Line Graph Showing Influence of COVID-19 on DHT adoption in trials*

**B) Questions asked to identify the types of Digital Health Technologies(DHTs) currently in use**

**Q3: Which Digital Health Technologies(DHTs) does your organization frequently use for Decentralized Clinical Trials (DCTs)?**

The survey data shows notable differences in DHT utilization between India and Ireland. In Ireland, telemedicine platforms (72.5%), remote monitoring devices (68.2%), and electronic health records (68.6%) were the most widely adopted technologies, with mobile health apps (62.7%) and e-consent platforms (64.7%) also showing strong adoption(Oracle, 2020; FDA, 2024a). Wearable devices were used by 49.0% of Irish respondents. In contrast, India reported lower adoption rates across all technologies, with remote monitoring devices (44.0%) and telemedicine platforms (42.4%) being most common. Notably, 30.3% of Indian respondents reported using no DHTs, while all Irish respondents utilized at least one technology. AI-based monitoring tools showed higher adoption in India (21.2%) than Ireland (11.8%), while blockchain for data security remained minimally used in both countries (India: 1.5%; Ireland: 3.9%). The findings demonstrate significantly broader DHT adoption in Ireland across all categories except AI-based tools.

*Table 4.2-8 Types of Digital Health Technologies used in DCTs*

| Types of Digital Health Technologies used in DCTs | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Telemedicine Platforms | 28 | 42.4% | 37 | 72.5% |
| e-Consent Platforms | 27 | 41.0% | 33 | 64.7% |
| Remote Monitoring Devices | 29 | 44.0% | 35 | 68.2% |
| Wearable Devices | 12 | 18.2% | 25 | 49.0% |
| Mobile Health Apps | 13 | 19.7% | 32 | 62.7% |
| AI-Based Patient Monitoring Tools | 14 | 21.2% | 6 | 11.8% |
| Electronic Health Records(EHRs) | 25 | 37.9% | 35 | 68.6% |
| Blockchain for Data Security | 1 | 1.5% | 2 | 3.9% |
| None | 20 | 30.3% | 0 | 0% |
| Total Respondents | 66 (100%) | | 51(100%) | |

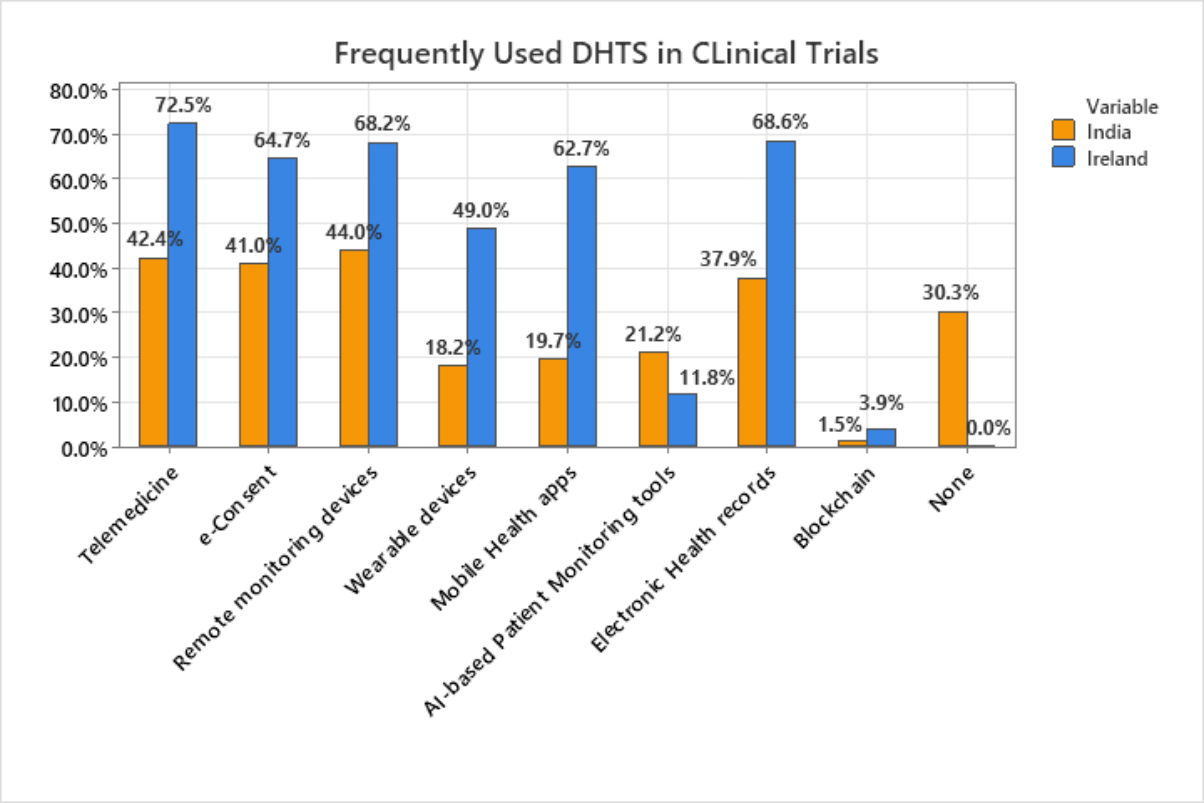



*Figure 4.2-11 Clustered Column Chart Showing Frequently used DHTs in Clinical Trials*

**Q4: What types of Telemedicine services does your organization currently use?**

The survey reveals significant differences in types of telemedicine use between countries. In Ireland, real-time video consultations dominate (76.5% adoption), followed distantly by store-and-forward (5.9%) and phone consultations (5.9%). Only 11.8% of Irish respondents reported no telemedicine use. India shows a more varied landscape: while real-time video leads (45.4%), phone consultations remain notable (16.7%), and store-and-forward is rare (1.5%). Notably, 40.9% of Indian respondents reported no telemedicine use. Both countries show minimal use of asynchronous store-and-forward telemedicine, suggesting synchronous methods (especially video) remain preferred when telemedicine is adopted(Cummins *et al.*, 2024). The data indicates Ireland's stronger use of video-based telemedicine.

*Table 4.2-9 Types of Telemedicine Platforms available*

| Types of Telemedicine | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Store-and-forward(asynchronous) | 1 | 1.5% | 3 | 5.9% |
| Real-time(synchronous) video consultations | 30 | 45.4% | 39 | 76.5% |
| Teleconsultation via phone/audio | 11 | 16.7% | 3 | 5.9% |
| None | 27 | 40.9% | 6 | 11.8% |
| Total Respondents | 66 (100%) | | 51(100%) | |

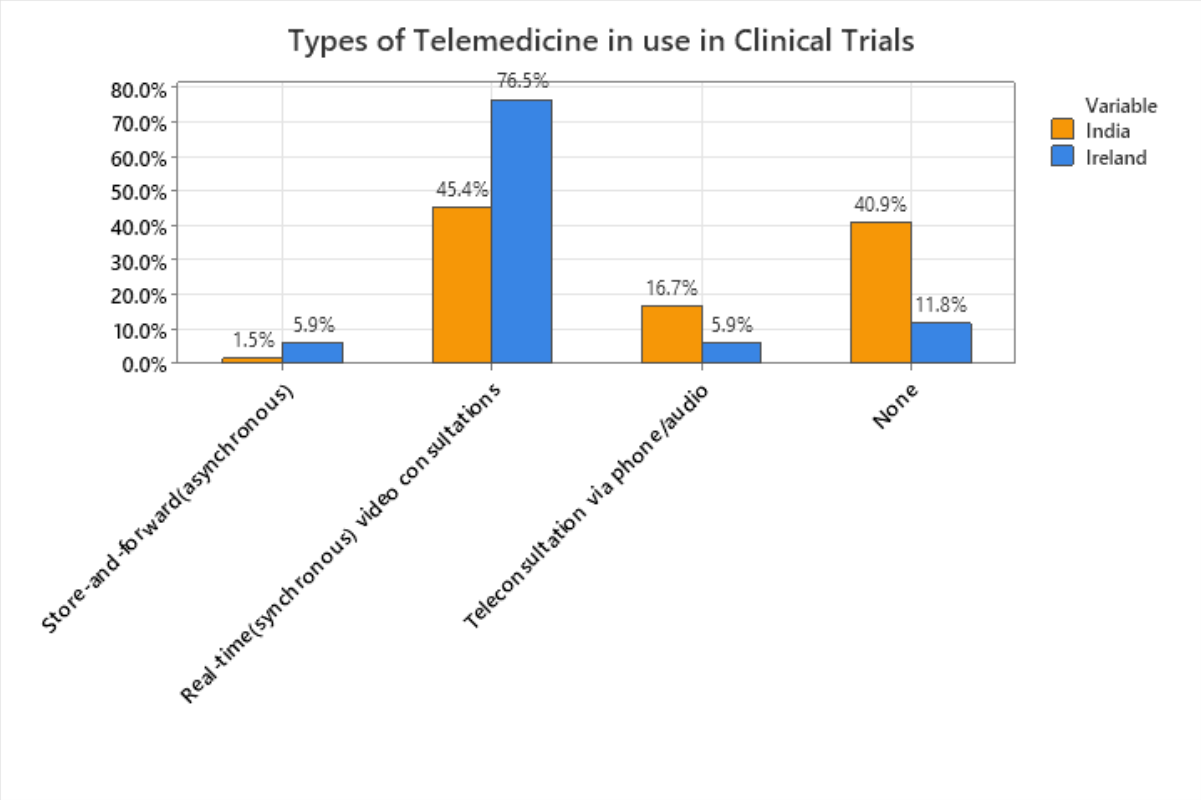



*Figure 4.2-12Clustered Column Chart Showing Types of Telemedicine Platforms*

**Q5: Which of the following telemedicine platforms does your organization use for Decentralized Clinical Trials?**

In Ireland, 66.7 % of respondents said that Zoom for Healthcare is used as their telemedicine platform, followed by Patients Know Best (21.5%). In India only 22.7% used Zoom for Healthcare as their telemedicine platform, followed by Apollo Telehealth (9.3%) and e-Sanjeevani (6.0%)(B, 2022; Sullivan, 2023; Medidata, 2025). Both countries show limited use of other platforms (all <10%), like Lybrate, Healthlink, MyClinic and Medidata in India and MyClinic in Ireland. Apart from these data, 54.5% of Indian respondents and 27.4% of Irish respondents reported that none of the above platforms were used in their organisation.

*Table 4.2-10 Examples of Telemedicine Platforms used for Clinical Trials*

| Country | Examples of Telemedicine Platforms Used in Clinical Trials | Frequency Count (No.) | Percentage distribution(%) |
|---|---|---|---|
| India | e-Sanjeevani | 4 | 6.0% |
| | Apollo Telehealth | 6 | 9.3% |
| | Lybrate | 2 | 3.0% |
| | Healthlink | 3 | 4.5% |
| | MyClinic | 2 | 3.0% |
| | Zoom for Healthcare | 15 | 22.7% |
| | None | 36 | 54.5% |
| | Others: Medidata | 1 | 1.5% |
| Total Respondents | | 66 | 100% |
| | DocOnline | 2 | 3.9% |
| | MyClinic | 1 | 1.9% |
| | Zoom for Healthcare | 34 | 66.7% |
| | Patients Know Best | 11 | 21.5% |
| | None | 14 | 27.4% |
| | Others: unknown | 1 | 2.0% |
| Total Respondents | | 51 | 100% |

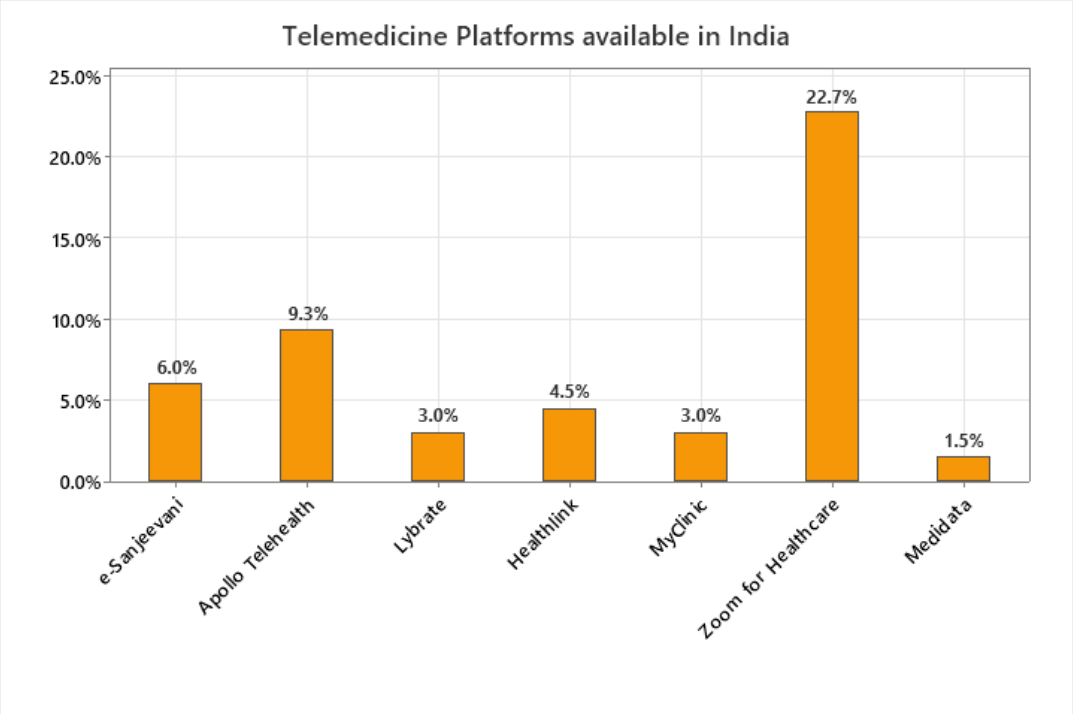



*Figure 4.2-13 Bar chart showing Telemedicine Platforms available in India*

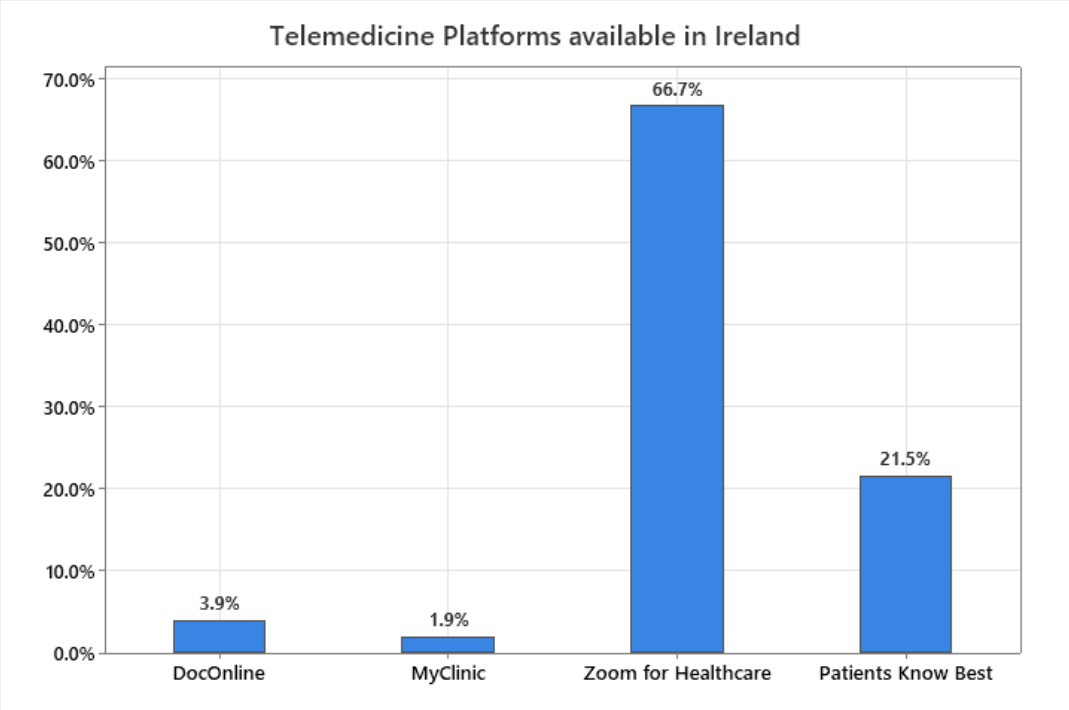



*Figure 4.2-14Bar chart showing Telemedicine Platforms available in Ireland*

**Q6: For Remote Monitoring Devices, which types does your organization most commonly use in for decentralized clinical trials ?**

The survey reveals significant differences in remote monitoring device usage between countries. Ireland shows consistently higher adoption rates across most devices: smartwatches (74.5%), blood pressure monitors (64.7%), and fitness trackers (45.1%) lead their device categories(FDA, 2024a; Quanticate, 2025). India demonstrates more moderate adoption, with smartwatches (45.4%) and blood pressure monitors (41.0%) being most common. Notably, 31.8% of Indian respondents reported using no remote monitoring devices compared to just 5.8% in Ireland. Some devices show higher adoption in India, including continuous glucose monitors (21.2% vs 13.7%), pulse oximeters (19.7% vs 11.8%), and ECG monitors (16.7% vs 7.8%). Both countries show minimal use of more specialized devices like sleep trackers, smart inhalers, and digital patches/biosensors (all <8%). The data indicates Ireland's broader and more intensive adoption of mainstream remote monitoring technologies compared to India's more selective adoption pattern**.**

*Table 4.2-11Frequently used Remote Monitoring Devices*

| Frequently Used Remote Monitoring Devices in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Continuous glucose monitors | 14 | 21.2% | 7 | 13.7% |
| Fitness trackers | 22 | 33.3% | 23 | 45.1% |
| Smartwatches | 30 | 45.4% | 38 | 74.5% |
| Blood pressure monitoring devices | 27 | 41.0% | 33 | 64.7% |
| Pulse oximeters | 13 | 19.7% | 6 | 11.8% |
| ECG monitors | 11 | 16.7% | 4 | 7.8% |
| Sleep Trackers | 5 | 7.6% | 2 | 3.9% |
| Smart Inhalers | 3 | 4.5% | 3 | 5.8% |
| Digital patches and Biosensors | 5 | 7.5% | 2 | 3.9% |
| None | 21 | 31.8% | 3 | 5.8% |
| Total Respondents | 66 (100%) | | 51(100%) | |

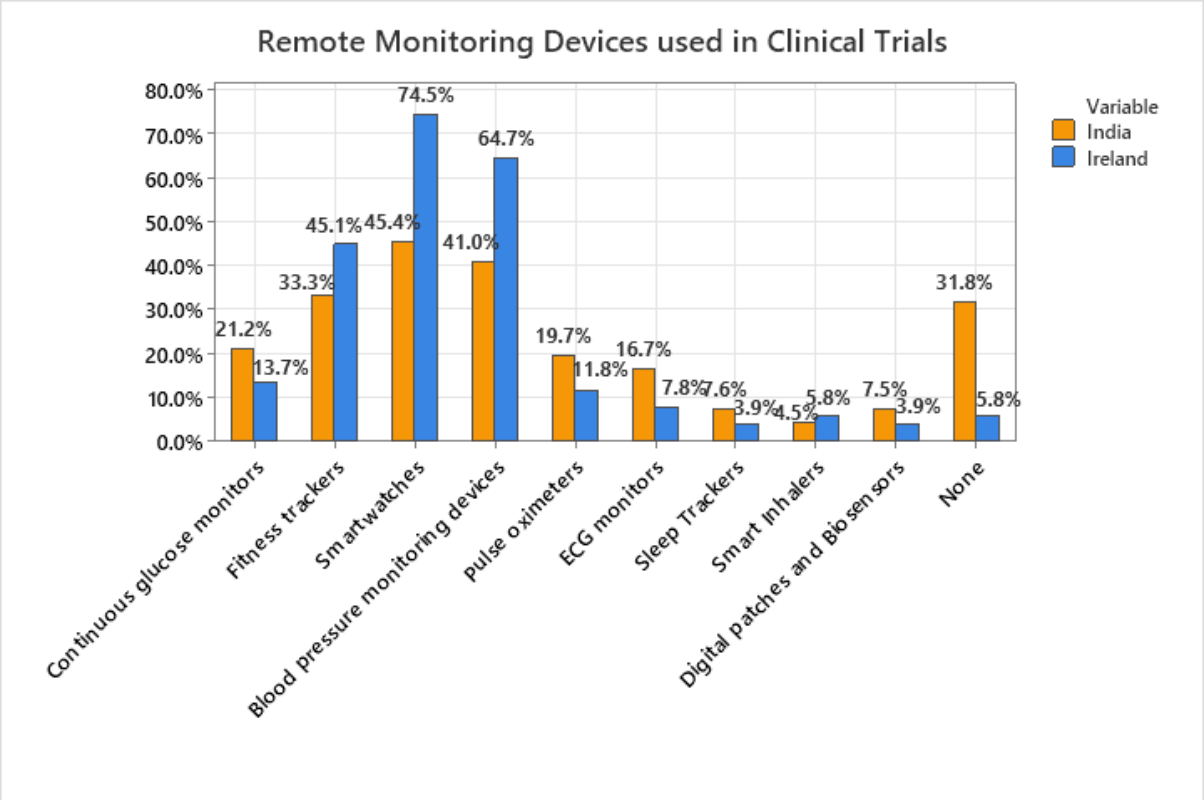



*Figure 4.2-15 Clustered Column Chart showing types of Remote Monitoring Devices*

**Q7: Which types of Mobile Health apps does your organization use in clinical trials?**

The survey shows significant differences in mobile health app usage between countries. Ireland demonstrates consistently higher adoption across all app categories: medication adherence apps (60.8%), patient-reported outcome apps (58.8%), symptom tracking apps (45.1%), and wearable integration apps (47.0%)(Kakkar *et al.*, 2018; WHO, 2025b). India shows more moderate adoption rates, with medication adherence apps being most common (37.9%), followed by patient-reported outcome and symptom tracking apps (both 30.3%). A notable 40.9% of Indian respondents reported using no mobile health apps, compared to just 19.6% in Ireland. The data reveals Ireland's broader and more intensive adoption of various mobile health applications in clinical trials, while India shows more limited but focused usage, particularly in medication adherence tracking.

*Table 4.2-12 Types of Mobile Health apps*

| Types of Mobile Health apps by different organizations | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Patient-reported outcome apps | 20 | 30.3% | 30 | 58.8% |
| Medication adherence apps | 25 | 37.9% | 31 | 60.8% |
| Symptom tracking apps | 20 | 30.3% | 23 | 45.1% |
| Wearable Integration apps | 18 | 27.2% | 24 | 47.0% |
| None | 27 | 40.9% | 10 | 19.6% |
| Total Respondents | 66 (100%) | | 51(100%) | |

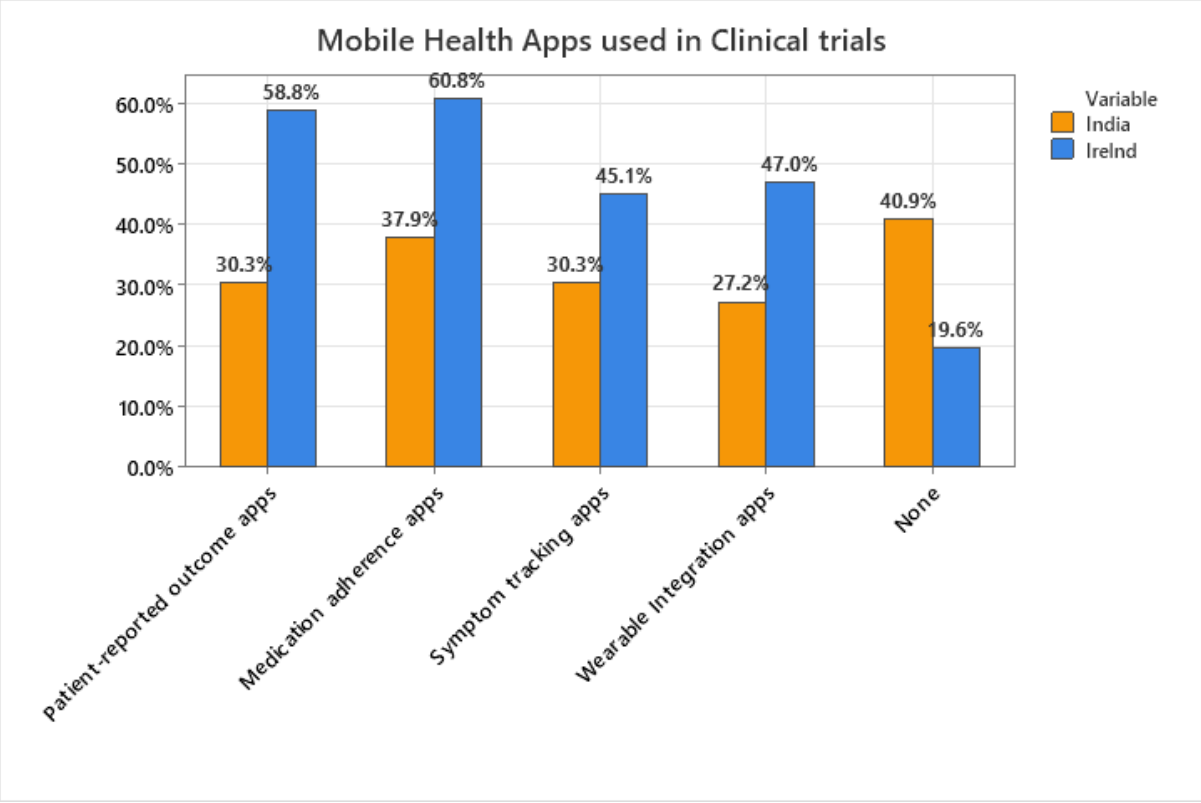



*Figure 4.2-16 Clustered Column Chart showing types of Mobile Health Apps*

**Analysis of Objective II:**

To evaluate the operational benefits and perceived impact of DHTs on key clinical trial outcomes, including patient recruitment, retention, data collection, and trial efficiency.

**Questions asked to Clinical Research Professionals- Clinical Research Associate, Clinical Data Manager, Clinical Trial Coordinator, Clinical Trial Assistant**

**Q8: What are the main opportunities of using telemedicine, remote monitoring devices, and mobile health apps in clinical trials?**

The survey reveals both similarities and differences in perceived DHT opportunities between countries. Real-time data collection was the most recognized benefit in both India (84.8%) and Ireland (78.4%). Other highly valued opportunities included improved patient engagement (India 66.7%, Ireland 74.5%) and increased patient convenience (India 68.9%, Ireland 66.7%). Notable differences emerged in several areas: Ireland placed greater emphasis on improved patient recruitment (58.8% vs 37.9%) and reduced site visits (68.6% vs 37.9%), while India more frequently cited better patient outcomes (51.5% vs 31.3%), enhanced communication (42.4% vs 17.6%), and better data accuracy (47.0% vs 31.4%).

Both countries showed moderate recognition of improved trial accessibility (~48%) and real-time feedback/alerts (India 54.5%, Ireland 41.2%). Cost-related benefits were less frequently identified, though India showed higher recognition of potential cost savings (27.3% vs 3.7%) and sponsor convenience (34.8% vs 2.0%). The findings suggest the core benefits of DHT adoption, like real-time collection, improved patient engagement, increased patient convenience, and patient recruitment rates(Mason Hayes & Curran, 2023; Oracle, 2025).

*Table 4.2-13 Benefits of using DHTs in Clinical Trials*

| Opportunities of using DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Real-time data collection | 56 | 84.8% | 40 | 78.4% |
| Improved patient engagement | 44 | 66.7% | 38 | 74.5% |
| Improved patient recruitment | 25 | 37.9% | 30 | 58.8% |
| Better patient outcomes | 34 | 51.5% | 16 | 31.3% |
| Increased convenience for patients | 45 | 68.9% | 34 | 66.7% |
| Reduced site visits for participants | 25 | 37.9% | 35 | 68.6% |
| Improved trial accessibility | 32 | 48.5% | 24 | 47.0% |
| Enhanced communication between patients and trial coordinators | 28 | 42.4% | 9 | 17.6% |
| Better data accuracy through remote monitoring | 31 | 47.0% | 16 | 31.4% |
| Real-time feedback and alerts | 36 | 54.5% | 21 | 41.2% |
| Increased cost savings | 18 | 27.3% | 19 | 3.7% |
| More convenient to sponsor | 23 | 34.8% | 10 | 2.0% |
| Total Respondents | 66 | | 51 | |

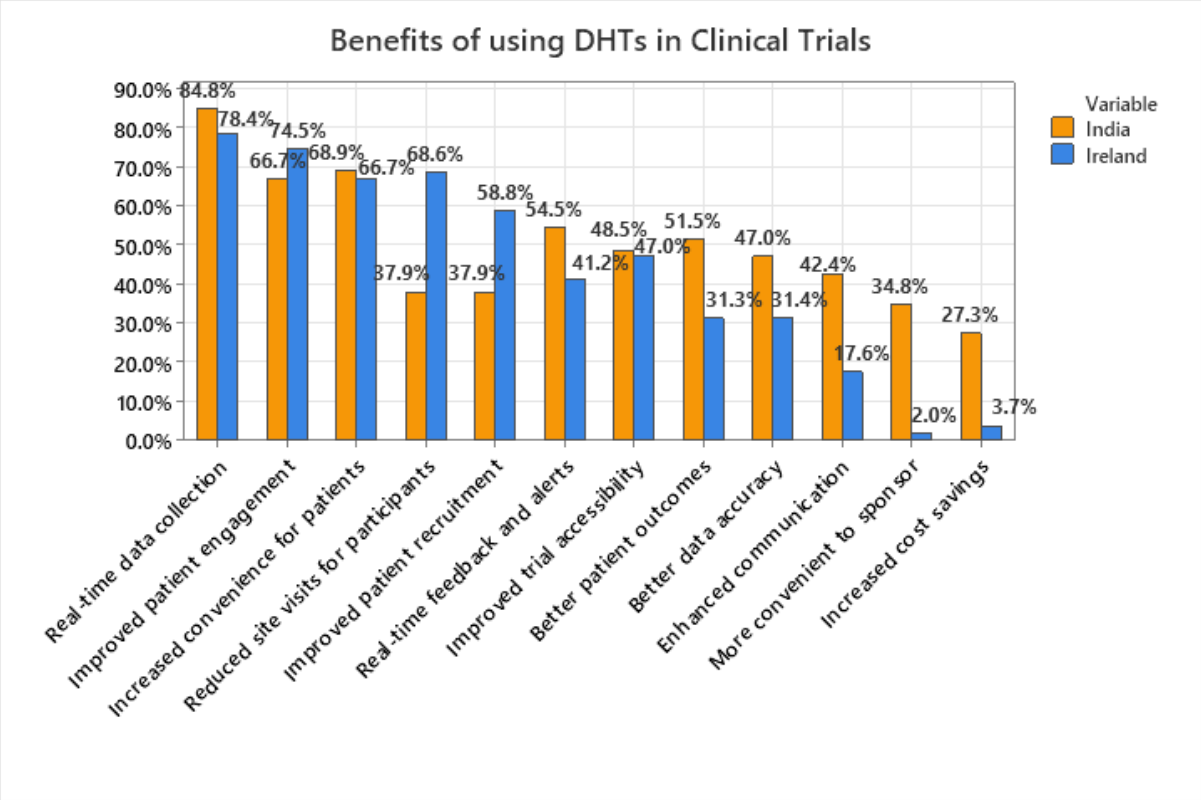



*Figure 4.2-17 Clustered Column Chart showing Benefits of using DHTs in clinical trials*

**Q9: What data does your organisation collect from participants using remote monitoring devices?**

The survey shows that heart rate (India: 47.0%, Ireland: 64.7%) and physical activity (India: 48.5%, Ireland: 74.5%) are the most commonly collected data types in both countries using remote monitoring devices, with Ireland demonstrating consistently higher utilization rates , followed by Medication adherence (India: 42.4%, Ireland: 60.8%)(Quanticate, 2025).

Blood glucose (India: 25.6%, Ireland: 21.5%) and sleep pattern (both countries: ~13.6%) monitoring show more comparable but lower adoption rates between nations. A striking difference appears in non-usage, where 30.3% of Indian respondents reported collecting no remote monitoring data, compared to just 2.0% in Ireland.

The data reveals that while both countries prioritize similar categories of health metrics (vital signs and activity data), Ireland demonstrates substantially more comprehensive adoption of remote monitoring across all measured parameters.

*Table 4.2-14 Data collected using Remote Monitoring Devices*

| Data collected using Remote Monitoring Devices | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Heart rate | 31 | 47.0% | 33 | 64.7% |
| Physical activity | 32 | 48.5% | 38 | 74.5% |
| Blood glucose | 17 | 25.6% | 11 | 21.5% |
| Sleep patterns | 9 | 13.6% | 7 | 13.7% |
| Medication adherence | 28 | 42.4% | 31 | 60.8% |
| Others: none | 20 | 30.3% | 1 | 2.0% |
| Total Respondents | 66 (100%) | | 51(100%) | |

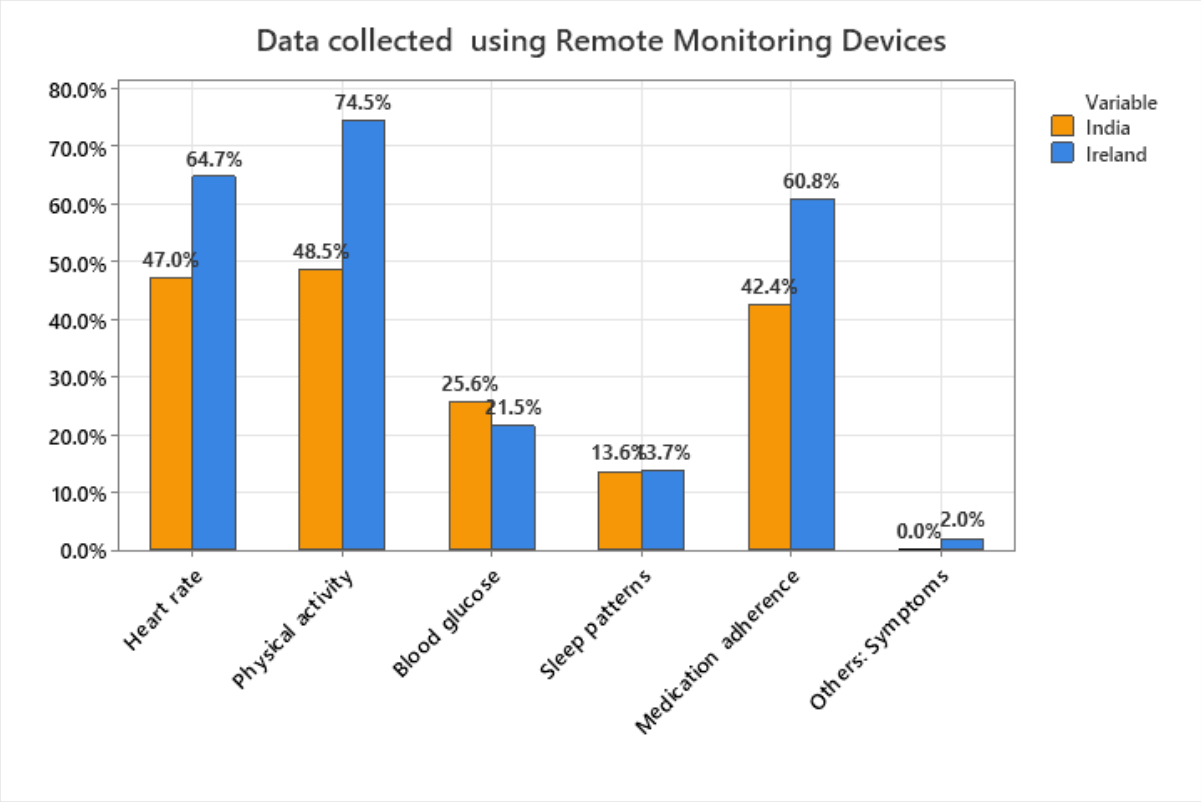



*Figure 4.2-18Clustered Column Chart showing types of data collected through remote monitoring devices*

**Q10: How do e-Consent platforms improve trial efficiency?**

The survey highlights several key benefits of e-consent adoption in clinical trials. The most widely recognized advantage is reduced paperwork, reported by 74.2% of respondents in India and 82.3% in Ireland. This is closely followed by a faster consent process (65.1% India, 80.4% Ireland) and broader patient reach (47.0% India, 78.4% Ireland). Other notable benefits include improved compliance with regulatory requirements (57.6% India, 64.7% Ireland), enhanced operational efficiency by reducing administrative burden (54.5% India, 68.6% Ireland)(Cragg *et al.*, 2024).

*Table 4.2-15 Benefits of e-Consent Platforms*

| Benefits of e-Consent Form | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Faster consent process | 43 | 65.1% | 41 | 80.4% |
| Broader patient reach | 31 | 47.0% | 40 | 78.4% |
| Reduced paperwork | 49 | 74.2% | 42 | 82.3% |
| Improved compliance with regulatory requirements | 38 | 57.6% | 33 | 64.7% |
| Improved operational efficiency by reducing administrative burden | 36 | 54.5% | 35 | 68.6% |
| Makes the approval process faster | 30 | 45.4% | 28 | 55.0% |
| Total Respondents | 66 (100%) | | 51(100%) | |

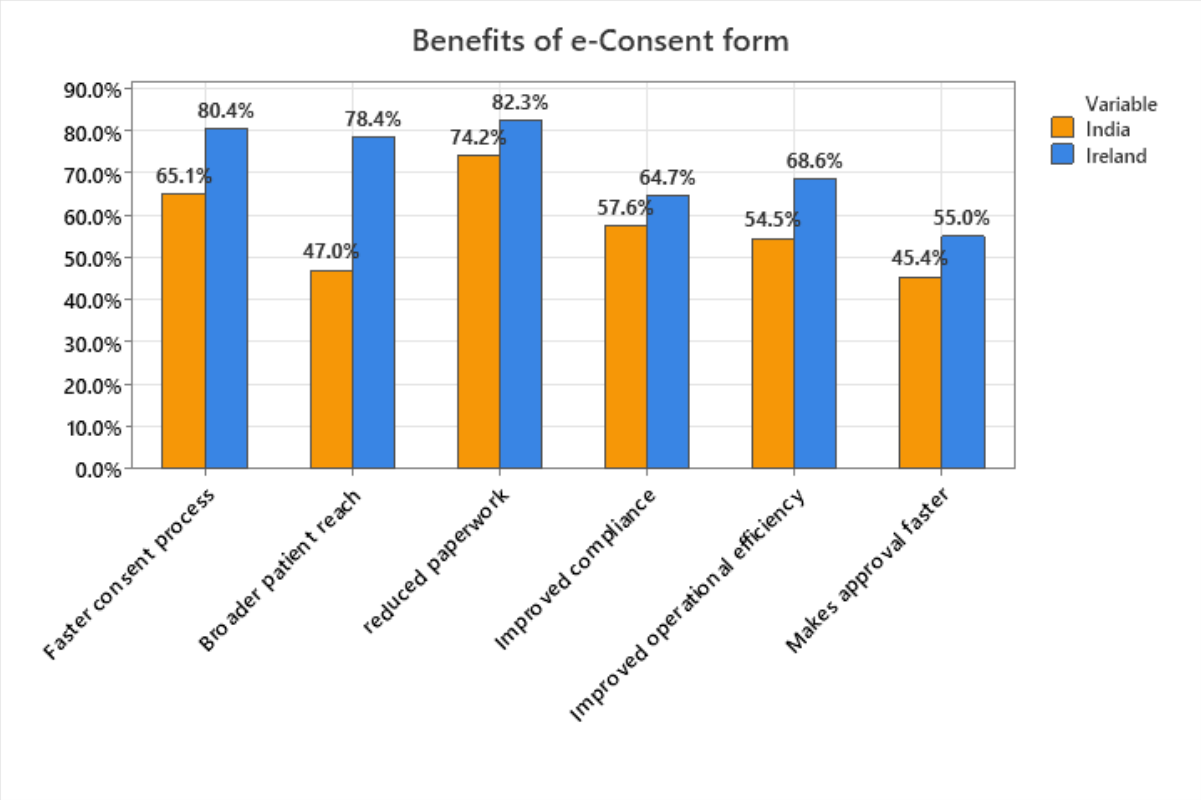



*Figure 4.2-19Clustered Column Chart showing benefits of e-Consent platform*

**Questions asked to Research Nurses**

**Q11:** How do patients generally respond to the use of DHTs?

Based on reports from research nurses (India: n=9; Ireland: n=7), patients in both countries responded positively to digital health technologies (DHTs) in clinical trials. All surveyed nurses in India observed either very positive (33.3%) or somewhat positive (66.7%) patient reactions. Irish nurses reported even stronger patient acceptance, with 71.4% observing very positive responses and 28.6% somewhat positive. No neutral or negative patient reactions were reported by nurses in either country. These findings suggest high patient receptiveness to DHTs, with slightly more enthusiastic adoption noted in Ireland.

*Table 4.2-16 Patient Response towards the use of DHTs*

| **Response of Patients to the use of DHTs** | **Country** | |
|---|---|---|
| | India | Ireland |
| Very Positively | 3(33.3%) | 5(71.4%) |
| Somewhat positively | 6(66.7%) | 2(28.6%) |
| Neutral | - | - |
| Somewhat negatively | - | - |
| Very negatively | - | - |
| Total Respondents | 9(100%) | 7(100%) |

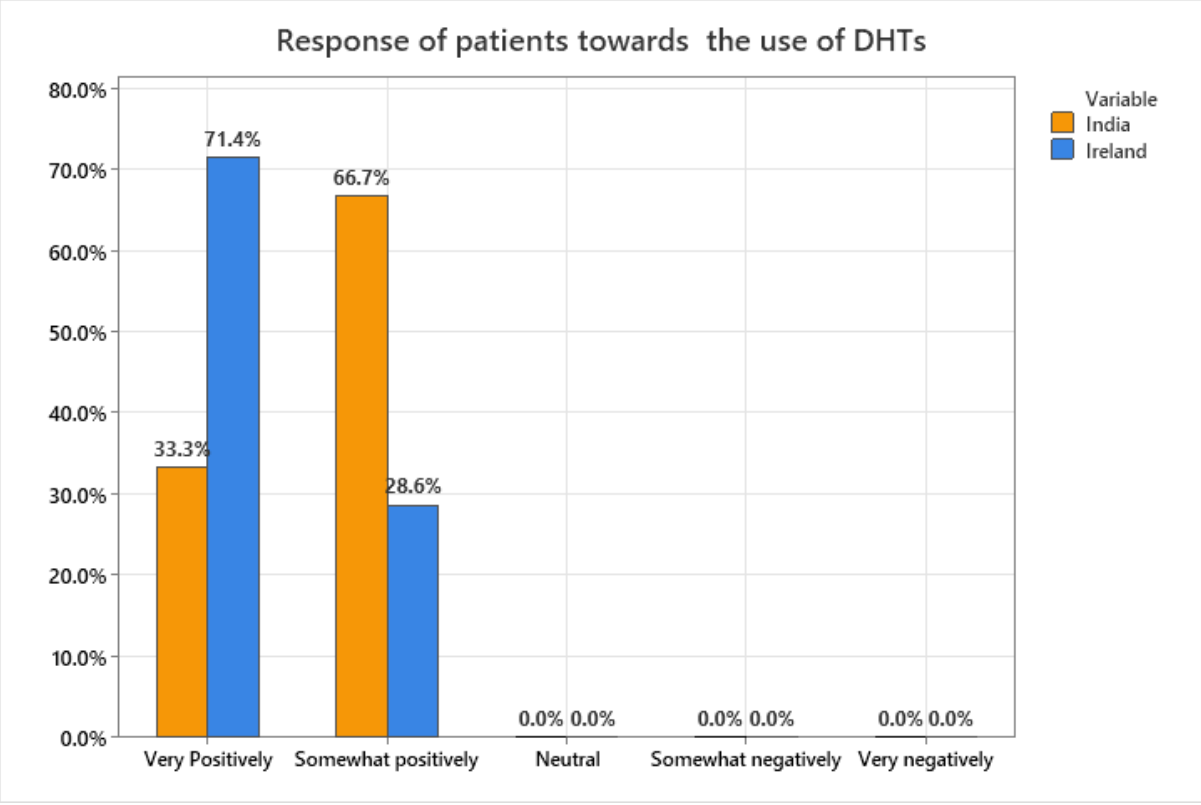



*Figure 4.2-20 Clustered Column Chart showing Response of patients towards use of DHTs*

**Q12: Do patients feel comfortable while using digital tools to monitor their health?**

Based on reports from research nurses (India: n=9; Ireland: n=7), patients in both countries responded positively to digital health technologies (DHTs) in clinical trials. All surveyed nurses in India observed either very positive (33.3%) or somewhat positive (66.7%) patient reactions. Irish nurses reported even stronger patient acceptance, with 71.4% observing very positive responses and 28.6% somewhat positive. No neutral or negative patient reactions were reported by nurses in either country. These findings suggest high patient receptiveness to DHTs, with slightly more enthusiastic adoption noted in Ireland.

*Table 4.2-17 Comfortable level of Patients towards the use of DHTs*

| **Comfortable level of Patients** | **Country** | |
|---|---|---|
| | India | Ireland |
| Very Comfortable | 3(33.3%) | 5(71.4%) |
| Somewhat comfortable | 5(55.5%) | 2(28.6%) |
| Neutral | 1(11.1%) | - |
| Not very comfortable | - | - |
| Not comfortable at all | - | - |
| Total | 9(100%) | 7(100%) |

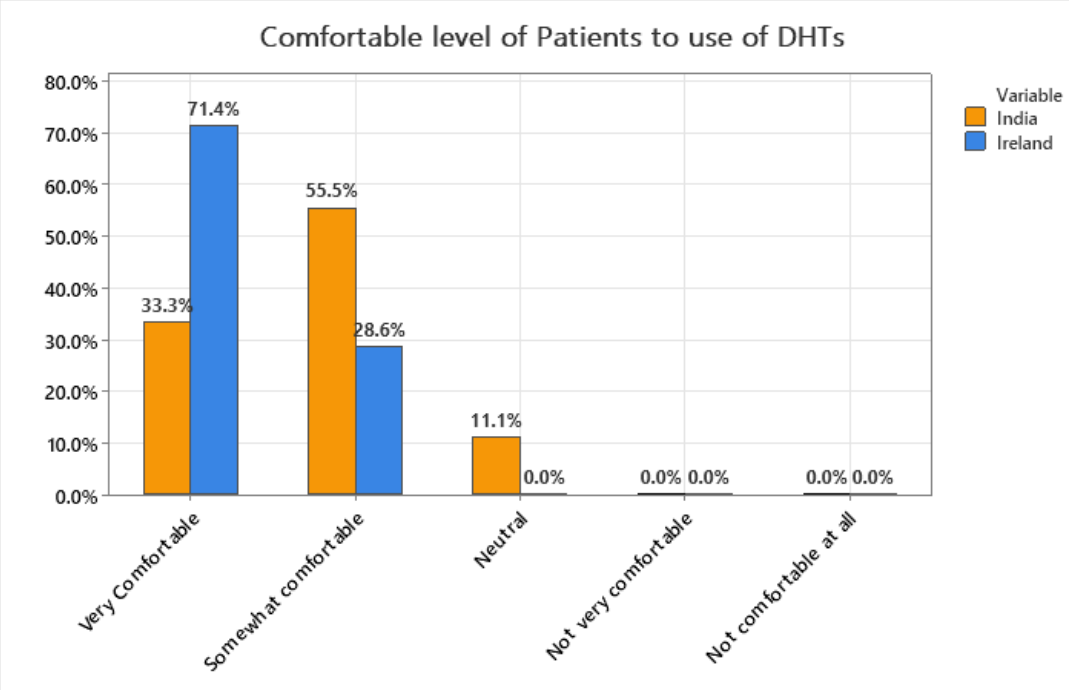



*Figure 4.2-21 Clustered Column Chart showing comfortable level of patients towards the use of DHTs*

# Analysis of Objective III:

To identify and analyse the key challenges that hinder the adoption of DHTs in DCTs across both regions.

**Q13: What are the key challenges of using Digital Health Technologies in clinical trials?**

The survey results reveal several key challenges in implementing digital health technologies (DHTs) across clinical trials in India and Ireland. Technical issues emerged as the most prevalent barrier, reported by 80.3% of Indian respondents and 68.6% of Irish respondents. India faces additional significant challenges including data privacy concerns (45.4%), patient-related issues (54.5%), lack of training/expertise (50%), and data reliability concerns (42.4%). In contrast, Ireland's primary challenge is lack of training/expertise (72.5%), followed by technical issues and patient-related challenges. Regulatory uncertainty appears more prominent in India (24.2%) than Ireland (17.6%), while staff resistance and workload increases are minor concerns in both countries (<10%). The findings reveal technical and training challenges as

universal barriers, with India facing greater data governance and patient-adoption issues, while Ireland's primary challenge is workforce upskilling. This underscores the need for country-specific implementation strategies(Apostolaros *et al.*, 2020; Whitelaw *et al.*, 2021; Clohessy *et al.*, 2024).

*Table 4.2-18 Key Challenges associated with use of DHTs*

| Key Challenges of Using DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Comparative lack of standardized regulatory guidelines | 16 | 24.2% | 9 | 17.6% |
| Data privacy concerns | 30 | 45.4% | 8 | 15.7% |
| Technical issues | 53 | 80.3% | 35 | 68.6% |
| Patient-related challenges | 36 | 54.5% | 22 | 43.1% |
| Ensuring data reliability and quality | 28 | 42.4% | 8 | 15.7% |
| Lack of training or expertise in DHTs | 33 | 50% | 37 | 72.5% |
| Resistance from clinical staff | 5 | 7.5% | 3 | 5.9% |
| Increased workload for clinical staff | 15 | 22.7% | 5 | 9.8% |
| Total Respondents | 66 (100%) | | 51(100%) | |

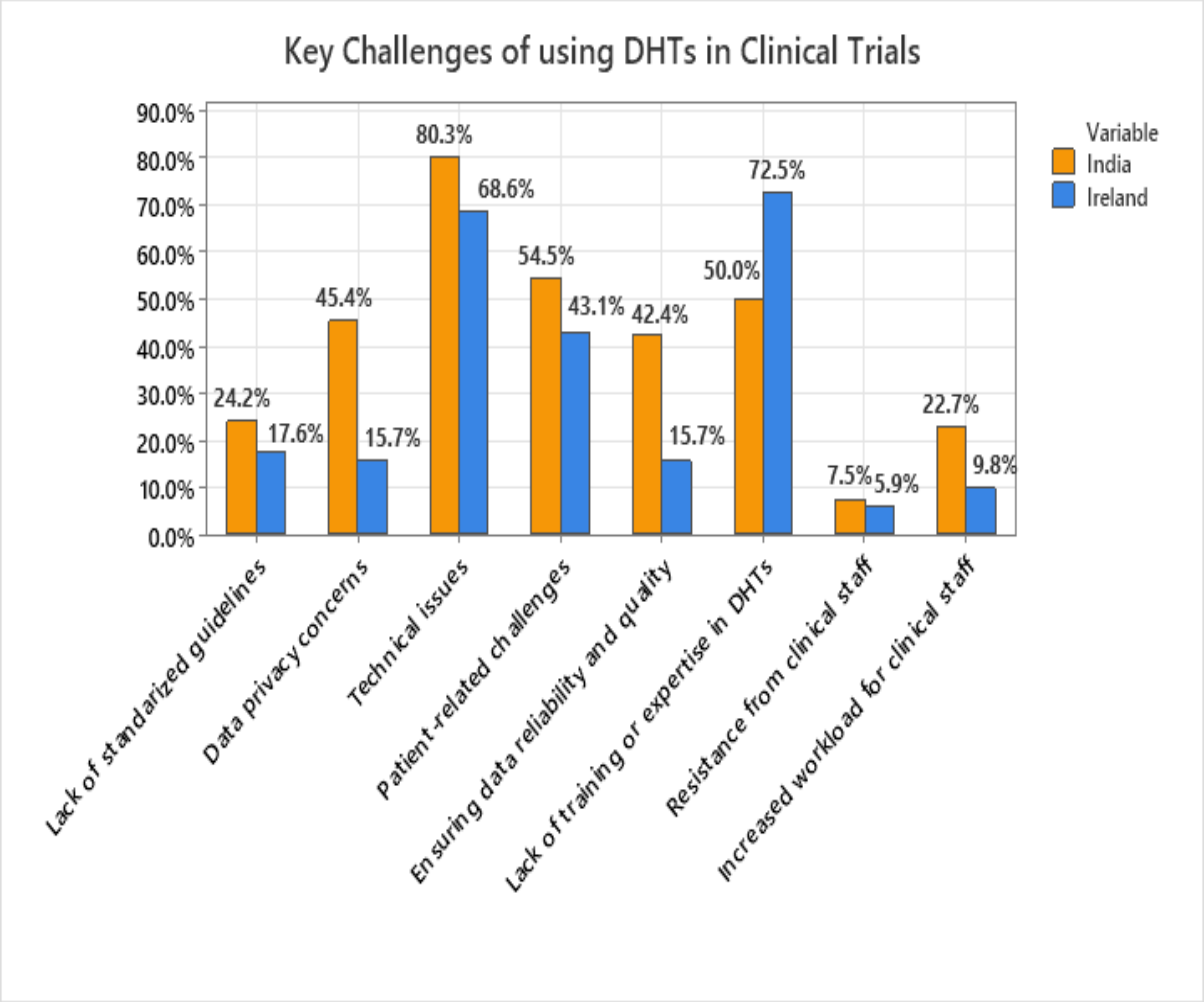



*Figure 4.2-22Clustered Column Chart showing Key Challenges faced during DHT implementation*

**Q14: What technical challenges has your organisation faced during the implementation of Digital Health technologies in Clinical Trials?**

The survey identified several technical challenges in implementing DHTs across clinical trials. In India, the most prevalent issues were lack of rural internet connectivity (36.4%) and software malfunctions (33.3%), while Ireland reported higher rates of software malfunctions (45.1%) and lack of troubleshooting expertise (33.3%). Both countries faced similar challenges with system integration (18-20%) and data synchronization (14-18%). Notably, about a quarter of respondents in each country reported no technical challenges (India 28.8%, Ireland 25.5%). These findings highlight infrastructure limitations as a key barrier in India versus technical

support needs in Ireland, suggesting different intervention priorities for each market(Clohessy *et al.*, 2024).

*Table 4.2-19Technical Challenges associated with use of DHTs*

| Technical Challenges of Using DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Difficulty integrating digital with existing system | 12 | 18.2% | 10 | 19.6% |
| Lack of internet connectivity in rural/ remote areas | 24 | 36.4% | 7 | 13.7% |
| Software malfunctions | 22 | 33.3% | 23 | 45.1% |
| Challenges in syncing data from multiple devices | 9 | 13.6% | 9 | 17.6% |
| Concerns about device accuracy and reliability of collected data | 4 | 6.1% | 4 | 7.8% |
| High maintenance cost | 10 | 15.1% | 3 | 5.9% |
| Lack of expertise or resources to troubleshoot technical issues | 9 | 13.6% | 17 | 33.3% |
| No Challenges | 19 | 28.8% | 13 | 25.5% |
| Total Respondents | 66 (100%) | | 51(100%) | |

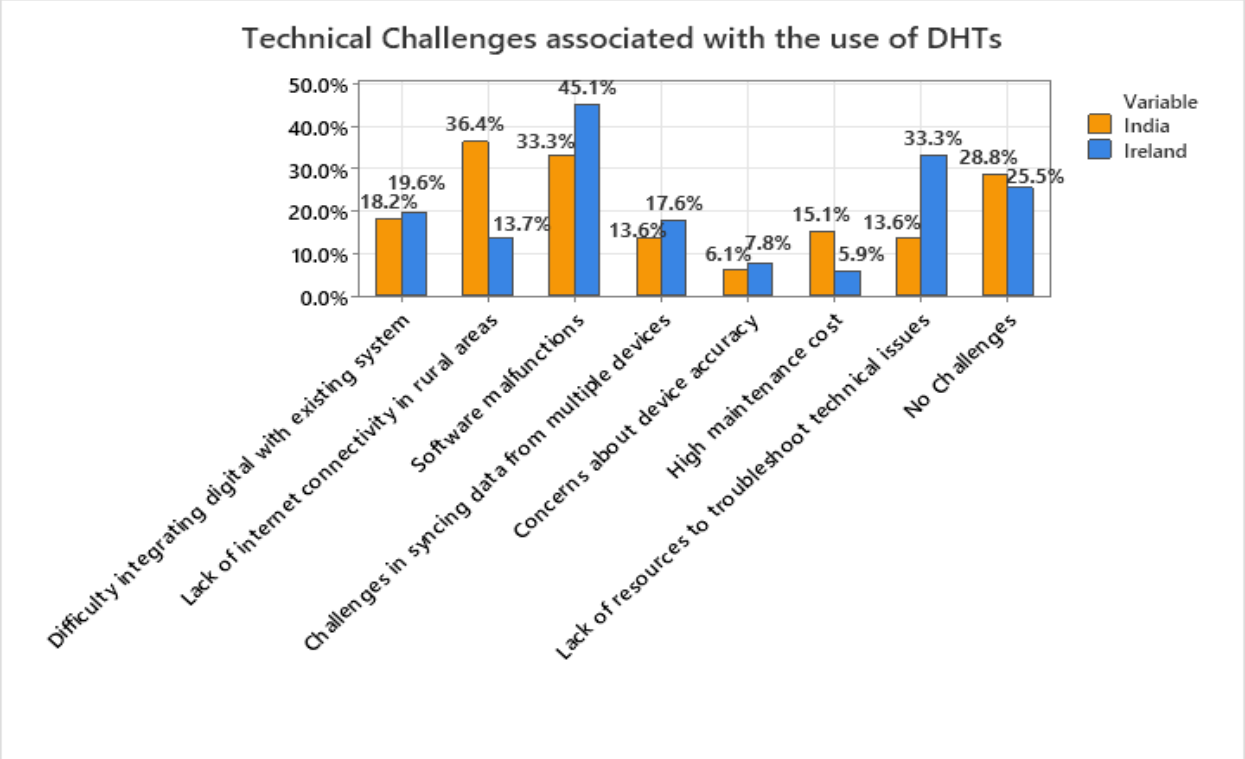



*Figure 4.2-23Clustered Column Chart showing technical challenges associated with the use of DHTs*

**Q15: What patient-related challenges has your organization faced during the implementation of Digital Health Technologies(DHTs) in clinical trials?**

The survey highlights distinct patient-related challenges in adopting digital health technologies (DHTs) between India and Ireland. In India, the primary barriers include limited digital literacy (41%), connectivity issues in rural areas (31.8%), and cultural/language barriers (24.2%), reflecting socioeconomic and infrastructural hurdles. Patients in India also report greater discomfort with wearables (25.7% vs 7.8% in Ireland) and face more technical difficulties during device setup (28.8% vs 11.7%). Conversely, Ireland's main challenge revolves around patient concerns regarding data security (33.3%). Notably, one-third of Irish respondents (33.3%) reported no patient challenges compared to 25.7% in India, suggesting more seamless adoption for certain populations. These findings underscore how India's adoption barriers stem largely from accessibility and education gaps, while Ireland's challenges centre on trust and acceptance of digital solutions. The results emphasize the need for tailored approaches: India may benefit from digital literacy initiatives and locally adapted designs, whereas Ireland might

focus on transparent data governance and patient education about technology safeguards(Rosa *et al.*, 2021; Clohessy *et al.*, 2024).

*Table 4.2-19 Patient-Related Challenges of using DHTs in Clinical Trials*

| Patient-Related Challenges of Using DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Limited digital literacy | 27 | 41% | 11 | 21.5% |
| Patients feel uncomfortable or hesitant to use wearables or other monitoring tools | 17 | 25.7% | 4 | 7.8% |
| Patients in rural or underserved areas face connectivity issues | 21 | 31.8% | 6 | 11.7% |
| Patients prefer traditional methods and are reluctant to adopt digital tools | 6 | 9.1% | 6 | 11.7% |
| Patients find it challenging to follow guidelines for using DHTs | 10 | 15.1% | 8 | 15.7% |
| Patients worry about the security of their health data | 14 | 21.2% | 17 | 33.3% |
| Patients with disabilities or chronic conditions may find it hard to use certain devices | 10 | 15.1% | 6 | 11.7% |
| Patients from diverse backgrounds may face challenges with language or culturally inappropriate designs. | 16 | 24.2% | 3 | 5.9% |
| Patients experience problems with device setup, connectivity, or functionality | 9 | 28.8% | 6 | 11.7% |
| No Challenges | 17 | 25.7% | 17 | 33.3% |
| Total Respondents | 66 (100%) | | 51(100%) | |

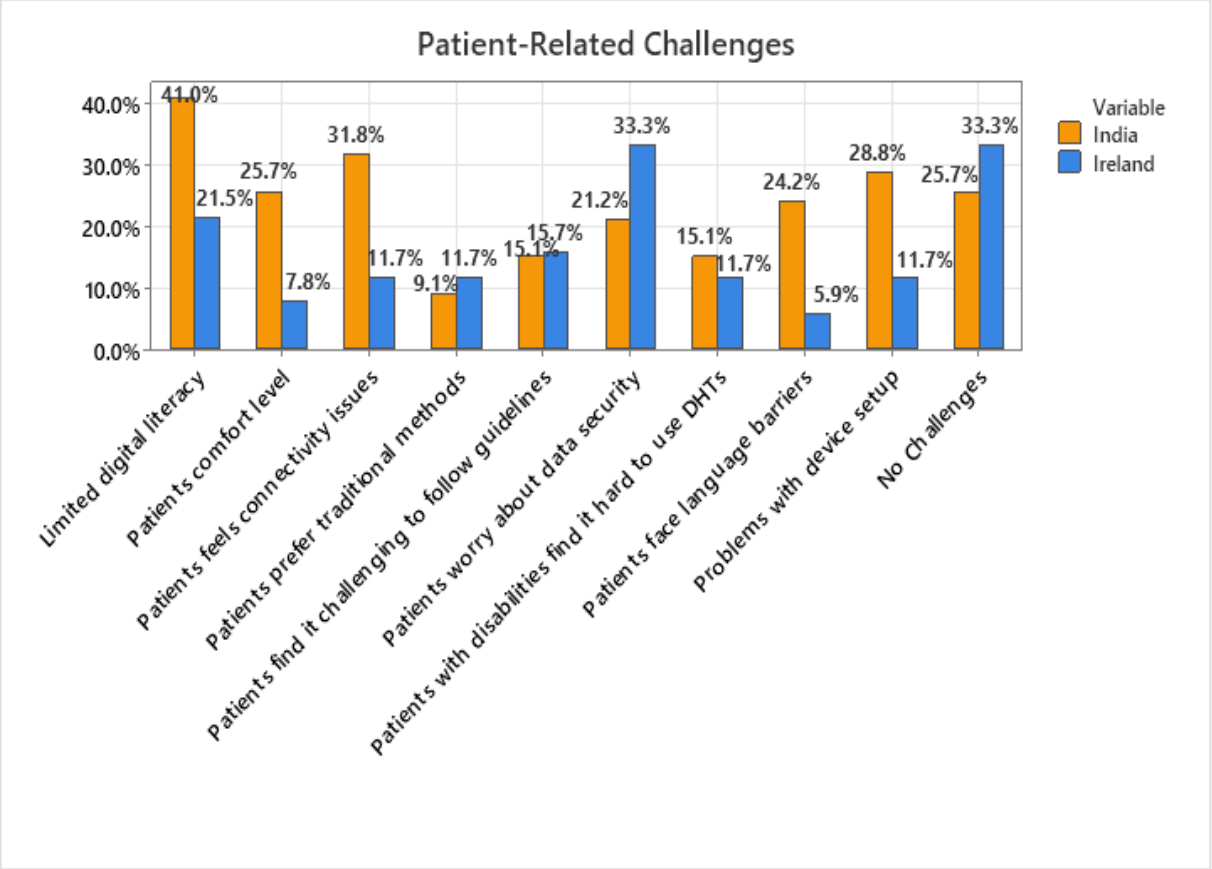



*Figure 4.2-24 Clustered Column Chart showing Patient-Related Challenges*

**Q16: Have you encountered any challenges related to data security or privacy concerns while using DHTs?**

The survey reveals most clinical trials using DHTs face minimal data security issues, with 62.1% of Indian and 78.4% of Irish respondents reporting no challenges. Key concerns include patient consent for data sharing (India 22.7%, Ireland 13.7%) and potential misuse by authorized personnel (7.5-9.8%). India reported additional minor concerns like accidental disclosures (7.5%) and cyber-attacks (3.0%), while Ireland showed slightly more issues with third-party data sharing (7.8% vs 4.5%). These findings suggest consent management and internal data governance remain primary focus areas, with Ireland demonstrating marginally stronger overall data protection(Whitelaw *et al.*, 2021; HSE, 2024).

*Table 4.2-20 Data security or Privacy challenges of using DHTs in Clinical Trials*

| Data Security or Privacy Challenges of Using DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Unauthorized access to patient data | 4 | 6.1% | 3 | 5.8% |
| Accidental disclosure of sensitive information | 5 | 7.5% | 2 | 3.9% |
| Data breaches from external cyber attacks | 2 | 3.0% | 0 | 0% |
| Misuse of data by authorized personnel | 5 | 7.5% | 5 | 9.8% |
| Lack of patient consent for data sharing | 15 | 22.7% | 7 | 13.7% |
| Systemic data flows to third parties without patient knowledge | 3 | 4.5% | 4 | 7.8% |
| Concerns about data storage and retention practices | 2 | 3.0% | 0 | 0% |
| No Challenges | 41 | 62.1% | 40 | 78.4% |
| Total Respondents | 66 (100%) | | 51(100%) | |

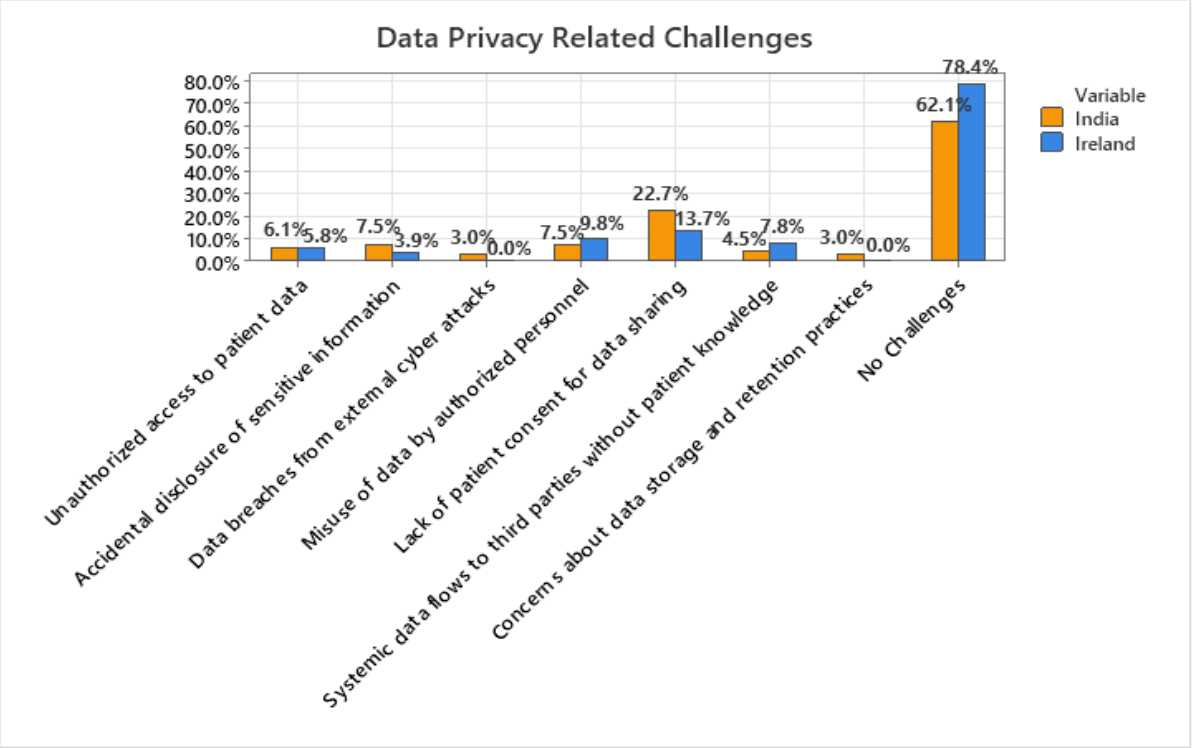



*Figure 4.2-25 Clustered Column Chart showing Data privacy concerns of using DHTs*

## Question asked to the Research Nurse

### Q17: What challenges do you think might prevent people from participating in Decentralized clinical trials?

According to research nurses (India: n=9; Ireland: n=7), the primary obstacle preventing patient participation is lack of DHT awareness (100% of Indian nurses, 85.7% Irish). Nurses also frequently reported patient privacy/security concerns (India 77.8%, Ireland 85.7%). Indian nurses noted technology access issues more often (22.2%) than their Irish counterparts (14.2%). Notably, only Irish nurses mentioned time commitment as a barrier (14.2%). These findings suggest nurses perceive patient education about DHTs and addressing privacy fears as crucial for improving trial participation(Whitelaw *et al.*, 2021).

*Table 4.2-21 Reasons that prevent people from participating in DCTs*

| Reasons that prevent people from participating in DCTs | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Time commitment | 0 | 0 | 1 | 14.2% |
| Lack of awareness of Digital Health technologies(DHTs) like remote monitoring devices, wearables, etc | 9 | 100% | 6 | 85.7% |
| Concerns about data privacy and security | 7 | 77.8% | 6 | 85.7% |
| Limited access to the internet or required technology | 2 | 22.2% | 1 | 14.2% |
| Total Respondents | 66 (100%) | | 51(100%) | |

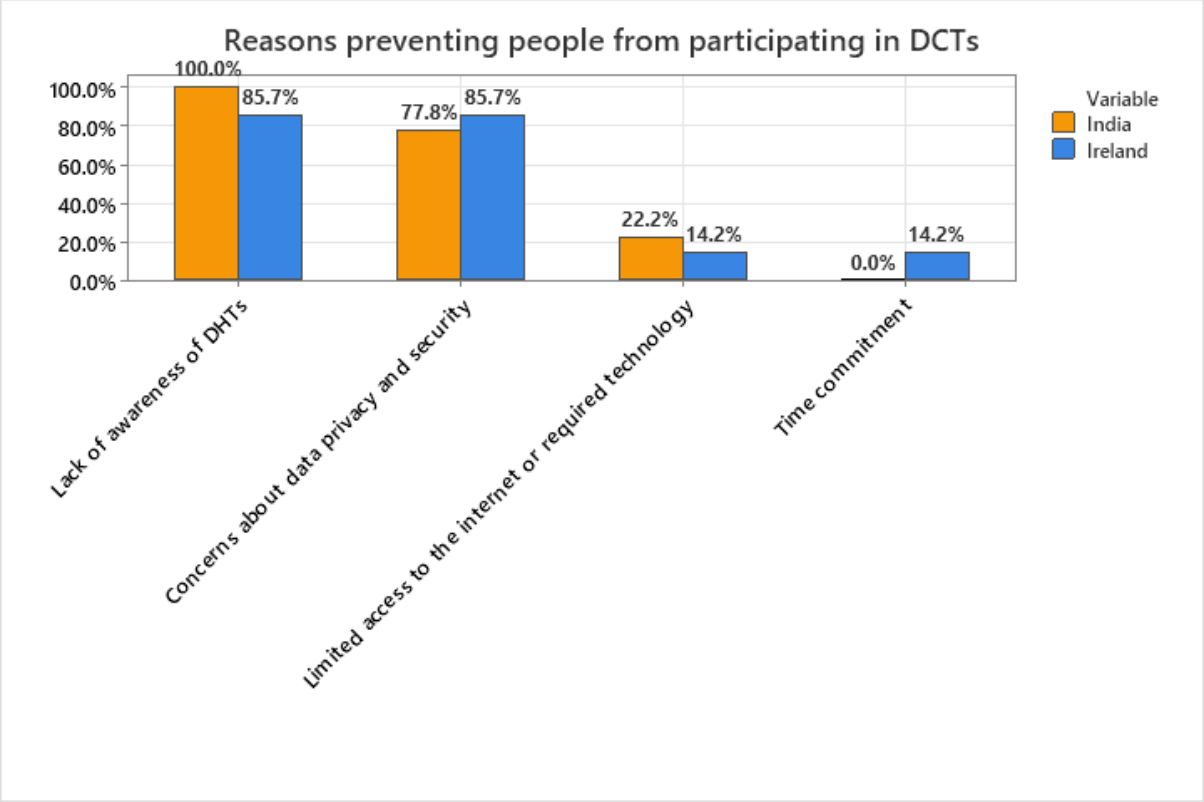



*Figure 4.2-26 Clustered Column Chart showing Reasons preventing people from participating in DCTs*

**Analysis of Objective IV:**

To evaluate the role of Contract Research Organizations (CROs) in integrating DHTs into DCTs in India and Ireland**.**

**Question asked to Clinical Research Professionals**

**Q18: How involved are Contract Research Organizations (CROs) in the implementation of DHTs in Decentralized Clinical Trials?**

The survey respondents report significant CRO engagement in both countries, with notable differences in intensity. In Ireland, 35.3% note "very involved" CROs versus 18.2% in India. Most respondents in both countries report at least "somewhat involved" participation (India: 62.1%; Ireland: 49.0%). Notably, 10.6% of Indian professionals indicate limited CRO involvement, while none in Ireland report low engagement. Neutral assessments are similar (9-14%). Findings reveal more intensive and consistent CRO involvement in Ireland, while India

shows greater variability. Both markets demonstrate substantial CRO participation, but Ireland's ecosystem appears more systematically engaged with research partners.

*Table 4.2-22 Contract Research Organization Involvement in adoption of DHTs in Clinical Trials*

| CROs Involvement in Clinical trials | Country | |
|---|---|---|
| | India | Ireland |
| Very Involved | 12 (18.2%) | 18(35.3%) |
| Somewhat involved | 41(62.1%) | 25(49.0%) |
| Neutral | 6(9.1%) | 7(13.7%) |
| Not very involved | 6(9.1%) | 0(0%) |
| Not involved at all | 1(1.5%) | 0(0%) |
| Total Respondents | 66(100%) | 51(100%) |

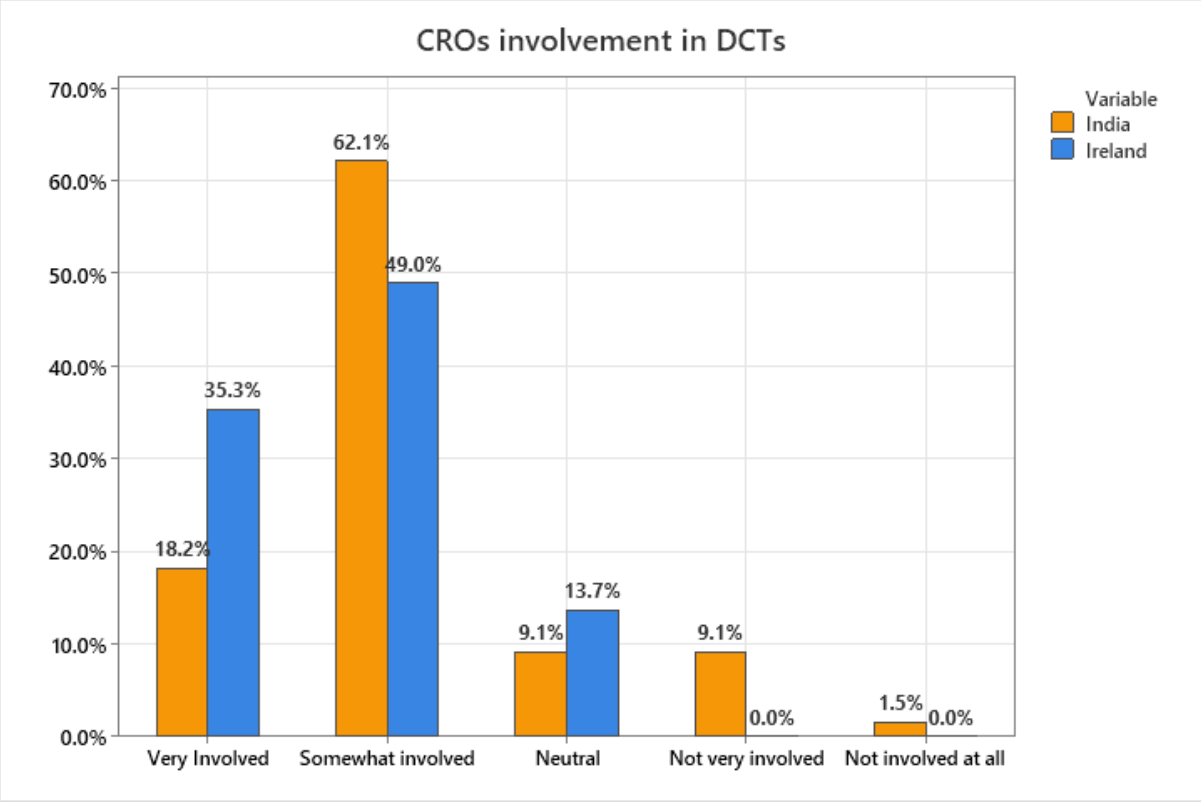



*Figure 4.2-27 Clustered Column Chart showing CRO involvement in Clinical Trials*

**Q19: Which of the following areas do CROs typically support in relation To DHTs in your trial?**

The respondents highlight CROs' crucial role in DCT implementation, particularly in data management and analytics (India: 77.3%; Ireland: 96.1%). Both countries show strong CRO involvement in technology selection (44-51%) and technical support (48-51%). While CRO involvement in participant training (India: 22.7%; Ireland: 21.5%) and regulatory compliance (India: 24.2%; Ireland: 17.6%) is less common but notable. A key difference emerges in non-involvement rates, with 18.2% of Indian respondents reporting no CRO participation versus just 3.9% in Ireland, underscoring more systematic CRO engagement in Ireland's DCT ecosystem(Reilly, 2021; Goverment of India (PMCF), 2023; Milo Healthcare, 2024).

*Table 4.2-23 Role of CROs in implementing DHTs in DCTs*

| Role of CROs in implementing DHTs in DCTs | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Selection and integration of DHT tools | 29 | 44.0% | 26 | 51% |
| Regulatory compliance and submissions | 16 | 24.2% | 9 | 17.6% |
| Participant onboarding and training | 15 | 22.7% | 11 | 21.5% |
| Data management and analytics | 51 | 77.3% | 49 | 96.1% |
| Technical support and troubleshooting | 32 | 48.5% | 26 | 51.0% |
| None of the above | 12 | 18.2% | 2 | 3.9% |
| Total Respondents | 66 (100%) | | 51(100%) | |

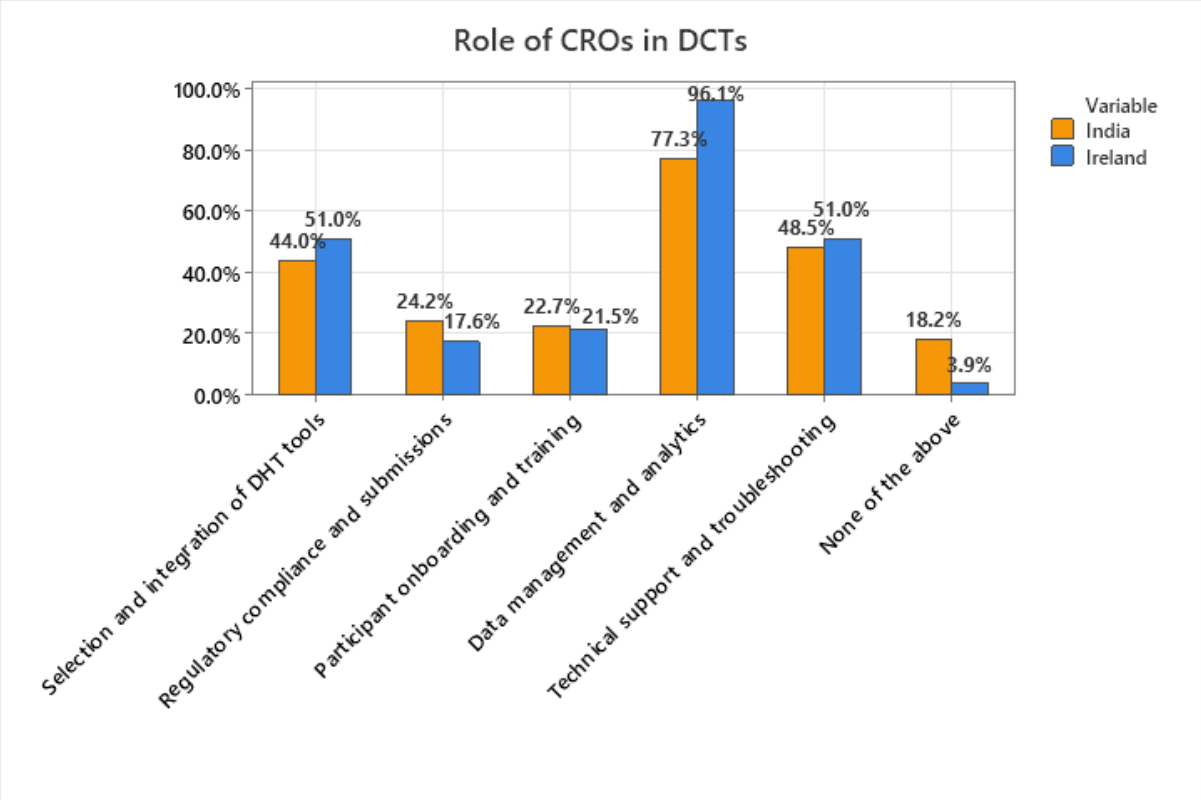



*Figure 4.2-28 Clustered Column Chart showing role of CROs in implementing DHTs*

**Analysis of Objective V:**

To identify emerging trends and future expectations for the adoption and expansion of DHTs in decentralized clinical research, based on stakeholder insights from both regions.

**Questions asked to Clinical Research Professionals**

**Q20: What do you think is the future of DHTs in Decentralized Clinical Trials?**

Industry professionals in both India and Ireland anticipate hybrid trials (combining DHTs with traditional methods) as the dominant future model (India: 71.2%; Ireland: 80.4%). While 24.2% of Indian respondents believe DHTs will become the universal standard, only 9.8% in Ireland share this view. Conversely, only 9.8% of Irish respondents predicted DHTs would remain niche or face adoption barriers, compared to ≤3% in India. The data suggests broad optimism for DHT integration, though primarily in hybrid formats rather than full replacement of traditional methods(Mckinsey, 2021).

*Table 4.2-24 Future of DHTs in Clinical Trials*

| Future of DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| DHTs will become the standard for all clinical trials. | 16 | 24.2% | 5 | 9.8% |
| DHTs will be used in combination with traditional methods (hybrid trials). | 47 | 71.2% | 41 | 80.4% |
| DHTs will remain niche and only be used in specific cases. | 1 | 1.5% | 5 | 9.8% |
| DHTs will face too many barriers to become widely adopted. | 2 | 3.0% | 5 | 9.8% |
| Total Respondents | 66 (100%) | | 51(100%) | |

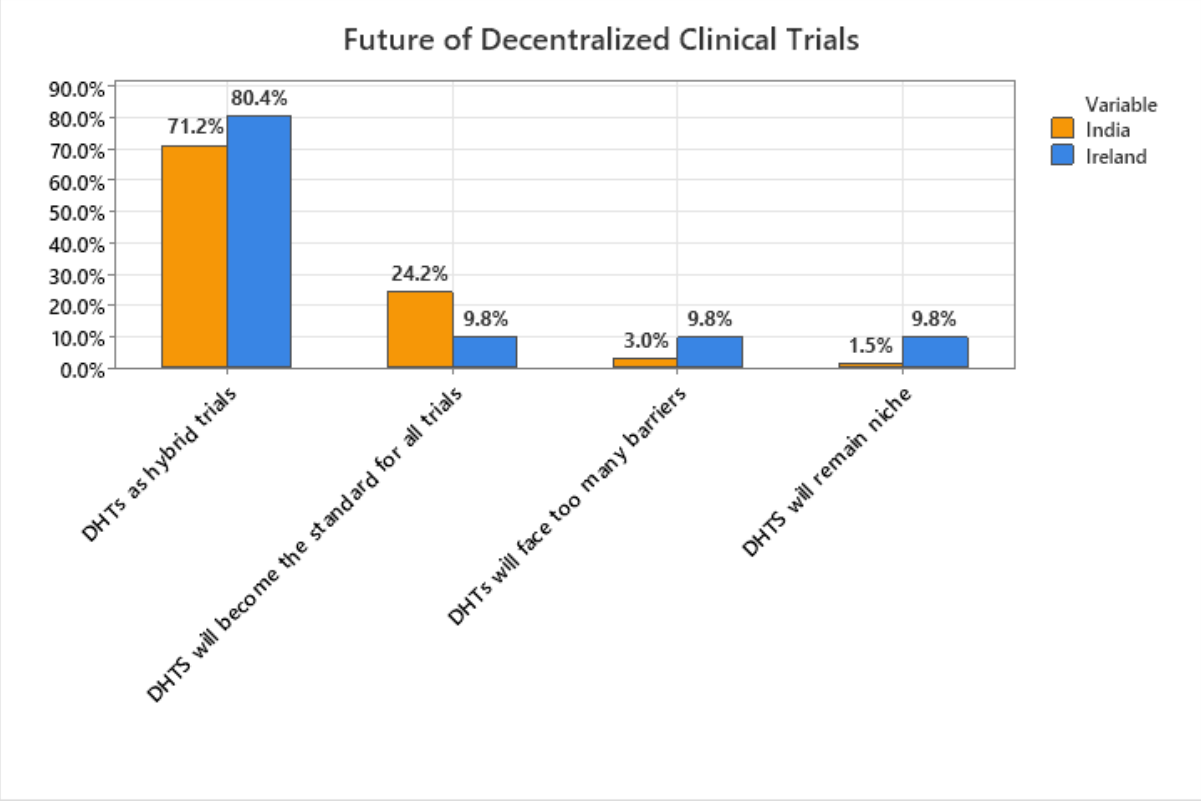



*Figure 4.2-29 Clustered Column Chart showing future of Clinical Trials*

**Q21**: **What emerging technologies do you believe will have the biggest impact on clinical trials in the next 5 years?**

The survey indicates Artificial Intelligence and Machine Learning will dominate clinical trials in both India (87.9%) and Ireland (84.3%) over the next five years, reflecting its critical role in data analysis and trial optimization. Advanced wearables and blockchain for data protection are also considered as the future tools , particularly in India (39.4% and 33.3%, respectively), though adoption may be slower in Ireland (23.5% for both). VR/AR remains experimental, with limited near potential (≤12.1% adoption). These trends suggest that while AI/ML will dominate future clinical trials(Califf and Rutherford, 2018; Rosa *et al.*, 2021).

*Table 4.2-25 Emerging Technologies in Clinical trials in the next five years*

| Emerging technologies | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Artificial Intelligence (AI) and Machine Learning (ML) | 58 | 87.9% | 43 | 84.3% |
| Blockchain for data security | 22 | 33.3% | 12 | 23.5% |
| Advanced wearable devices | 26 | 39.4% | 12 | 23.5% |
| Virtual and Augmented Reality (VR/AR) | 8 | 12.1% | 4 | 7.8% |
| Total Respondents | 66 (100%) | | 51(100%) | |

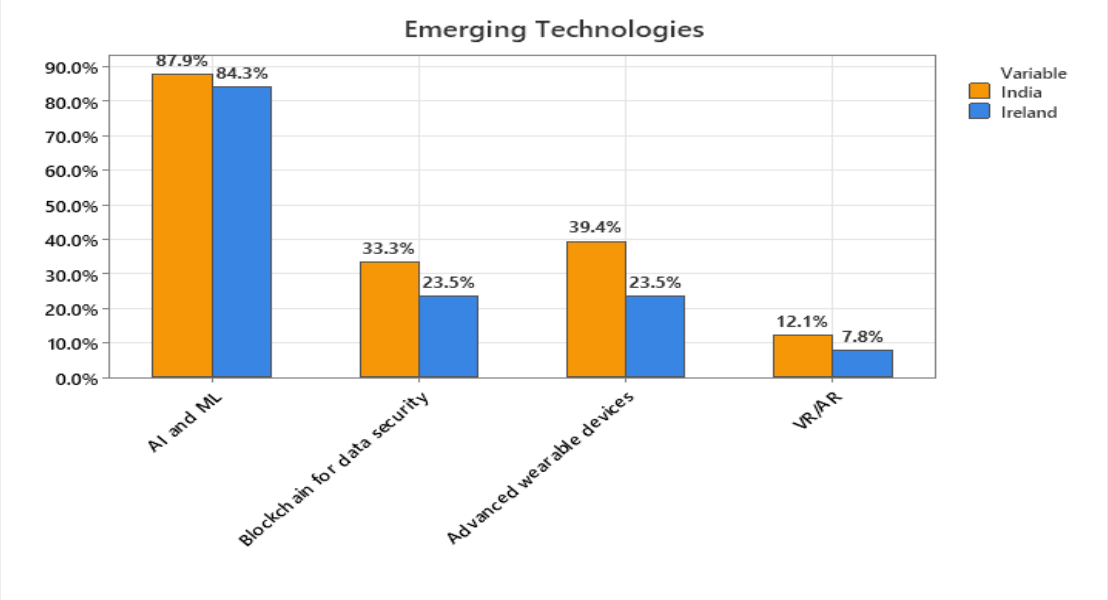



*Figure 4.2-30 Clustered Column Chart showing emerging technologies in the next five year*

**Analysis of Objective VI:**

To provide actionable recommendations for CROs, sponsors, and regulators to optimize the use of DHTs in DCTs.

**Q22**: **What measures do you think could improve patient engagement and trust in telemedicine and remote monitoring devices?**

Survey results show that 78.8% of Indian and 78.4% of Irish professionals prioritize educational campaigns to enhance patient engagement with digital health technologies. User-friendly interfaces are also critical, supported by 69.7% in India and 78.4% in Ireland. While 66.6% of Irish respondents emphasize patient training programs, only 45.4% in India share this view. Feedback mechanisms show similar divergence (62.7% Ireland vs 45.4% India). Personalized support is less prioritized (27.2% India, 23.5% Ireland), likely due to scalability challenges. These findings highlight universal needs for patient education and user-friendly design, with Ireland placing greater emphasis on training and feedback systems.

*Table 4.2-26 Measures to improve patient engagement and trust in DHTs*

| Measures to improve patient engagement and trust in DHTs | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Educational campaigns to increase awareness and understanding of digital health tools. | 52 | 78.8% | 40 | 78.4% |
| Creating user-friendly interfaces by simplifying the design of apps and devices for ease of use. | 46 | 69.7% | 40 | 78.4% |
| Providing training for patients on how to use telemedicine and remote monitoring tools. | 30 | 45.4% | 34 | 66.6% |
| Providing personalized support by offering one-on-one assistance for patients unfamiliar with technology. | 18 | 27.2% | 12 | 23.5% |
| Providing feedback mechanisms to patients to share their experiences and suggest improvements. | 30 | 45.4% | 32 | 62.7% |
| Total Respondents | 66 (100%) | | 51(100%) | |

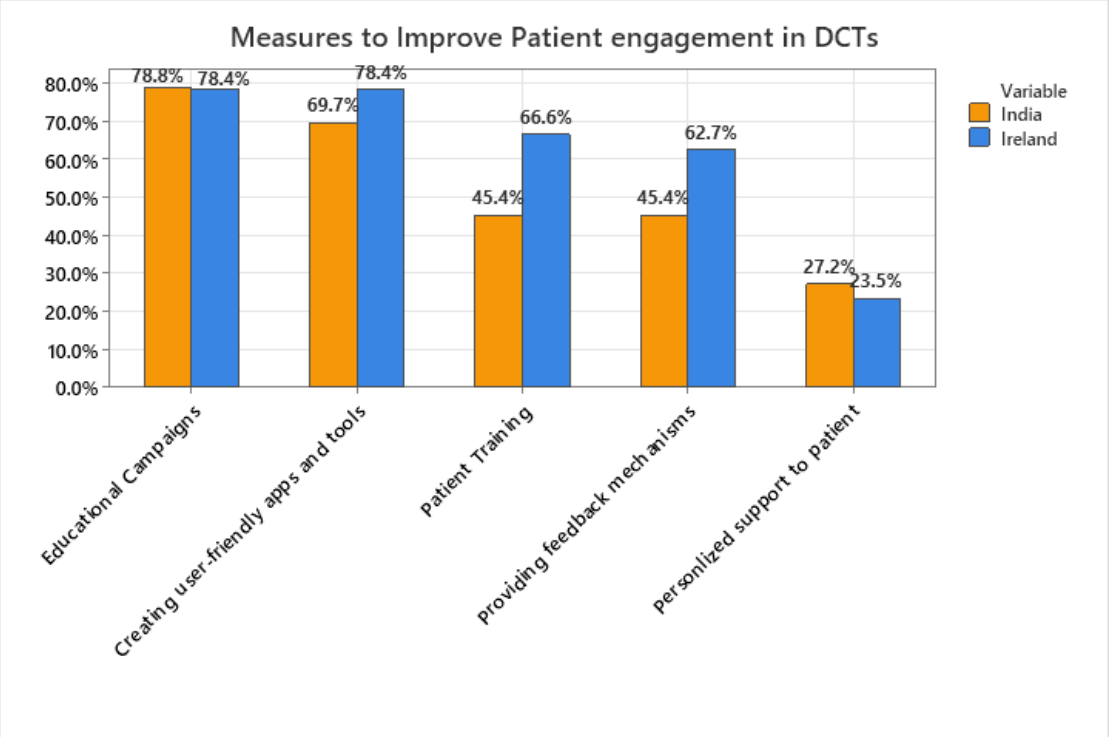



*Figure 4.2-31Clustered Column Chart showing the measures to improve patient engagement*

**Q23: What recommendations would you suggest for governments to improve the adoption of DHTs in Clinical Trials?**

The survey results reveal key recommendations to enhance the adoption of digital health technologies (DHTs) in clinical trials across India and Ireland. The most widely supported strategy in both countries involves conducting training and awareness programs to improve digital literacy, endorsed by 65.1% of Indian respondents and 58.8% of Irish professionals. Infrastructure investment, particularly in internet connectivity for rural areas, was also strongly recommended (53.0% India, 58.8% Ireland). Notable differences emerge in other approaches: public-private partnerships with tech companies received much stronger support in Ireland (70.6%) compared to India (37.9%), while India placed relatively more emphasis on developing clear guidelines for DHT use (41.0% vs 31.4% in Ireland). Data protection measures showed the largest disparity, with 52.9% of Irish respondents prioritizing strengthened laws compared to just 27.2% in India. These findings suggest that while digital education and infrastructure are universal needs, Ireland favours collaborative and regulatory solutions, whereas India may benefit more from structured guidance and expanded access initiatives. The results provide a framework for tailored implementation strategies that address each country's distinct adoption challenge.

*Table 4.2-27 Recommendations to improve adoption of DHTs in clinical trials*

| Recommendations to improve adoption of DHTs in Clinical Trials | Country | | | |
|---|---|---|---|---|
| | India | | Ireland | |
| | Frequency Count (No.) | Percentage distribution(%) | Frequency Count (No.) | Percentage distribution(%) |
| Provide clear guidelines for the use of digital health tools in clinical trials. | 27 | 41.0% | 16 | 31.4% |
| Investing in internet connectivity and digital infrastructure, especially in rural areas. | 35 | 53.0% | 30 | 58.8% |
| Developing Public-private partnerships by collaborating with tech companies to develop digital health solutions. | 25 | 37.9% | 36 | 70.6% |
| Conducting training and awareness programs to improve digital literacy among healthcare providers and patients. | 43 | 65.1% | 30 | 58.8% |
| Strengthening laws to protect patient data and ensure compliance (e.g., GDPR, DPDP Act). | 18 | 27.2% | 27 | 52.9% |
| Total Respondents | 66 (100%) | | 51(100%) | |

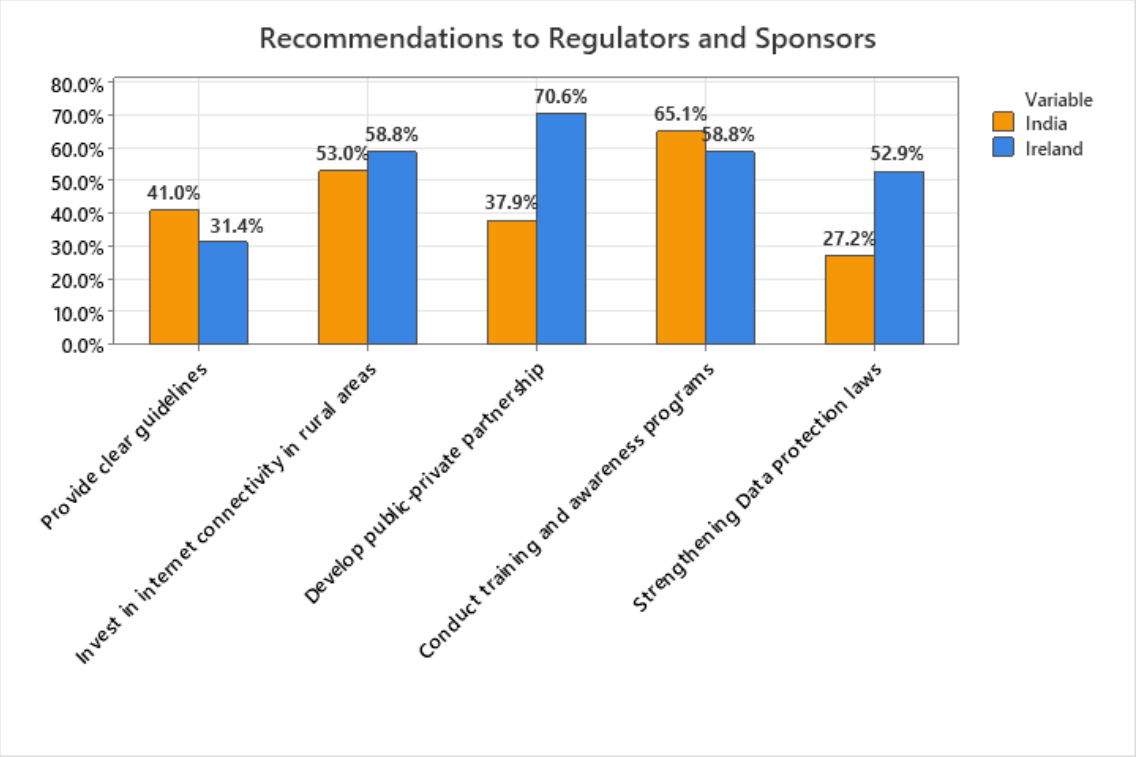



*Figure 4.2-32Clustered Column Chart showing recommendations to regulators and sponsors*

**Q24: What other recommendations would you give to regulators, sponsors, and CROs to improve the adoption of DHTs in DCTs?(open-ended question)**

The open-ended responses revealed distinct priorities between Indian and Irish clinical trial professionals regarding DHT adoption. Indian respondents consistently highlighted infrastructure limitations, particularly in rural areas, emphasizing the need for improved connectivity and digital literacy programs to support basic adoption. Multiple responses stressed the importance of developing simplified, user-friendly interfaces to leverage India's smartphone penetration while accommodating diverse literacy levels. Regulatory clarity emerged as another key concern, with participants calling for tailored frameworks to govern DHT implementation. Irish professionals, while equally concerned with training and usability, focused more on optimizing existing systems through public-private partnerships and ensuring GDPR-compliant data governance. Their recommendations frequently mentioned co-design methodologies and system interoperability, reflecting a more mature digital health ecosystem. Both groups strongly advocated for patient-centered design principles, though Indian responses tended to address fundamental accessibility barriers while Irish suggestions focused on enhancing existing digital infrastructure and collaboration models. The findings underscore how DHT implementation strategies must adapt to regional technological capabilities and

healthcare system architectures while maintaining core commitments to usability and comprehensive training.

*Table 4.2-28 Recommendations by Survey Respondents to improve DHT adoption in India*

| Country | Other Recommendations |
|---|---|
| India | *Investment in internet connectivity, developing public-private partnerships, conducting training and awareness programs in such a way where the CD is more valid and the patients are also free from fear* |
| | *Conducting training and awareness programs to improve digital literacy among healthcare providers and patients* |
| | *Regulators need to develop clear regulatory frameworks that specifically address the use of DHTs in trials* |
| | *To adopt more DHTs in clinical trials to make it more convenient to participants* |
| | *Implement a good regulatory framework when adopting DHTs.* |
| | *Provide robust training and technical support to both trial staff and participants using DHTs.* |
| | *Improve confidentiality and privacy of the participant's data* |
| | *To make digital health tools a natural part of decentralized trials, regulators can offer clearer guidance and help ensure different systems work well together. At the same time, sponsors and CROs should focus on making the experience easier for patients, support sites with training, and work closely with all partners to build trust and keep things running smoothly.* |
| | *Bring out what is more effective for DHTs, Digitalization will be easy to have complete data in hands* |
| | *Invest in digital infrastructure supporting data integration, real-time monitoring, provide robust training for both participants and clinical trial site staff to ease the use of DHTs.* |
| | *India has second largest smart phone user in world and has a large population of people using electronic device , by providing a robust ,elemental , simple and easy design , which can be easily understandable and approachable to common people, adoption of DHTs would be efficiently done , by that way we will get mega information about healthcare. From this data we can easily do digital clinical trial as precautious step for drugs which have harmful ADR before entering clinical trial .* |
| | *By infusing AI into DHTs , it would be more helpful for prevention and cure* |
| | *Design patient friendly app for ease of use* |

*Table 4.2-29 Recommendations by Survey Respondents to improve DHT adoption in Ireland*

| Country | Recommendations |
|---|---|
| Ireland | *Provide clear guidelines for the improvement of DHT*<br>*Investment in the internet in rural areas* |
| | *Developing public-private relationships* |
| | *Improvement in technology* |
| | *Design patient-friendly apps for easy use* |
| | *Provides robust training for both participants and clinical trial staff to ease the use of DHTs* |
| | *Improve awareness among health professionals, provide adequate training, and make them patient-friendly* |
| | *Conduct awareness programs for patients and trial staffs on the use of digital tools in clinical trials* |
| | *Invest more in digital infrastructure supporting data integration.* |
| | *Proper funding and education* |
| | *Co-designing DHTs and adoption strategies/resources with patients and lay members of the public.* |
| | *Providing both training for participants and clinical trials staff to ease the use of DHTs* |
| | *To be more precise with updated SOPs* |

## 4.3 QUALITATIVE DATA ANALYSIS

As outlined in the methodology chapter, this study employed Braun and Clarke's (2006) thematic analysis approach to examine the qualitative data collected from clinical research professionals in India and Ireland. Thematic analysis is a flexible method that allows for the identification, analysis, and reporting of recurring patterns (themes) within qualitative data(Braun and Clarke, 2006; Naeem *et al.*, 2023). This approach is particularly well-suited for exploring potential topics and gathering significant insights from the perspectives and personal experiences of the professionals

A total of five semi-structured interviews were conducted for the qualitative component of this study—three with participants from India and two from Ireland. All participants had more than three years of professional experience in clinical research and were involved in diverse roles such as Clinical Data Manager, Clinical Data Coordinator, and Clinical Research Nurse. The aim was to capture a broad range of insights from professionals directly engaged in various stages of clinical trial operations.

The first step in the analysis involved the transcription of interview recordings. The transcripts were carefully reviewed to correct any errors or misspellings and ensure clarity. For ease of

reference, the interviewer was labeled as “I” and each respondent as “R” within the transcripts. Each interview was also assigned a unique identifier—PIN (Participant India) for Indian respondents and PIR (Participant Ireland) for Irish respondents.

The qualitative data were analysed manually through a structured coding process. Responses were carefully read and re-read to identify meaningful segments of text, which were then grouped into initial codes. These codes were further refined and categorized into broader themes and sub-themes, providing a systematic framework for interpretation(Maguire and Delahunt, 2017). A total of seven major themes emerged from this process, directly contributing to the research objectives and offering valuable insights into the lived experiences of clinical research professionals.

This thematic analysis offered in-depth insights into participant perspectives on the benefits and challenges of DHTs, the role of Contract Research Organizations (CROs), and future considerations for DCTs. Manual coding allowed for close engagement with the data, and supporting visual aids such as summary tables and charts were used to illustrate the frequency and relevance of key themes. Most of the findings were consistent with existing literature, further validating the perspectives gathered.

Overall, this qualitative analysis added depth and richness to the study, enabling a multidimensional understanding of the evolving landscape of decentralized clinical trials in India and Ireland.

**Interview Participants**

*Table 4.3-1 List of Interview Participants*

| Participants(code) | Country | Participant Role | Experience |
|---|---|---|---|
| Participant 1 (PIN1) | India | Clinical Data Manager | 5+ years |
| Participant 2 (PIR1) | Ireland | Clinical Nurse Manager | 5 years |
| Participant 3 (PIN2) | India | Research Nurse | 6 years |
| Participant 4 (PIR2) | Ireland | Research Nurse | 9 years |
| Participant 5 (PIN3) | India | Clinical Data Coordinator | 3+ years |

## Themes and Codes

This section presents the main themes and sub-themes that emerged from the qualitative analysis of the interview data. The analysis process began with a detailed review of key words and phrases from each participant's responses. These keywords were grouped based on similarity and relevance, which led to the identification of sub-themes. The sub-themes were then further refined and categorized under broader main themes, each of which aligns closely with the study's research objectives and research questions.

This thematic structure allowed for a clear and systematic presentation of the findings. The relationships between key ideas were explored through iterative coding and comparison, helping to highlight common patterns as well as unique insights across the interviews. The development of themes ensured that the participants' perspectives were meaningfully represented and grounded in the context of decentralized clinical trials and digital health technologies.


*Figure 4.3-1Word Cloud of Participant's interviewed (Created using NVivo Software)*

The following table outlines the main themes and corresponding sub-themes that were identified during the qualitative analysis.

*Table 4.3-2 Thematic analysis of Interview Response*

| Theme | Sub-Themes | Key words | Supporting Quotes (Examples) | Linked Objective(s) |
|---|---|---|---|---|
| **1. Adoption and Types of DHTs used** | i)Growth of DHT in Clinical Trials<br><br>ii) Types of DHTs | • COVID-19<br>• Wearable devices<br>• Telemedicine<br>• MFine<br>• ECOA<br>• Electronic Data Capture<br>• e-Consent<br>• Remote monitoring devices<br>• Continuous blood pressure monitor<br>• Continuous glucose monitor<br>• Medidata<br>• Hypoglycaemic e-Diaries<br>• Mobile apps<br>• Symptom tracking<br>• ECG patches | **PIN1**-"I think after COVID, this has become one of the technologies that has helped clinical trials"<br><br>"wearable devices used to test the blood pressure levels"<br><br>"all the study related visit details directly into the EDC'<br><br>"ECOA-electronic clinical outcome assessment platform wherein the data collected from the wearable devices will straight go to the ECOA platform"<br><br>**PIR2**-"So this current study that I'm talking about, we do have informed consents and participant information leaflet It's all online"<br><br>"for example, like monitoring of clinical like vital signs and outcomes. So in this particular study we have like for example like measuring blood pressure for the patient."<br><br>**PIN2-"**And in the last couple of years, especially during the time of the COVID pandemic. I have been a part of the clinical trial'<br><br>"most of our trials are now also site based But we have started integrating the mobile health apps, remote follow-ups for patient who cannot travel frequently and all"<br><br>"Where the patient entered their daily glucose ratings into a mobile app, our site team reviewed this data every week. And also we also only call the patients if they their readings were abnormal"<br><br>"apps for symptom tracking and also for medication reminders" | **Objective I**: To assess the current level of adoption and types of Digital Health Technologies (DHTs)—such as telemedicine, e-consent, remote monitoring, and wearable devices—used in decentralized clinical trials (DCTs) in India and Ireland.<br><br>**Objective II**: To evaluate the operational benefits and perceived impact of DHTs on key clinical trial outcomes, including patient recruitment, retention, data collection, and trial efficiency. |

| | | | | |
|---|---|---|---|---|
| | | | "REDcap for EDC , MFine for virtual consultations" | |
| | | | PIR2- over the past three years there has increase in the use of digital tools in trials after COVID-19<br><br>Wearable ECG patches to monitor real-time heart rhythm<br><br>Blood pressure monitoring Used Fitbit watch | |
| | | | **PIN3**<br>Continuous glucose monitor sent to patient home and they record the recording to mobile app daily, patients were also asked to record the time they took the IMP<br><br>Weight tracking and recording of other vital through fitness trackers | |
| **2. Benefits of DHTs in Decentralized Clinical Trials** | i) Improved Patient recruitment<br><br>ii) Enhanced Patient engagement<br><br>iii) Enhanced Data collection<br><br>iv) Real-time monitoring<br><br>iii) Improve Inclusivity<br><br>v) Reduced workload<br><br>vi) Reduced patient visit<br><br>vii) Enhanced ADR detection<br><br>viii) Improved environmental sustainability | • Paperless approach<br>• Reduced manual work<br>• Patient's comfort zone<br>• Real time data<br>• Adverse events<br>• Symptom tracking<br>• Medication adherence<br>• Improve inclusivity | **PIN1-**"Patient's recruitment to get at a faster rate now"<br><br>"because of the digital health platforms, we are able to reach out at the comfort zone of the patients"<br><br>"The device helps in collecting the data on real time basis"<br><br>"So one of the studies that we are doing, we literally have a paperless approach will be directly enter the patient information, all the study related visit details directly into the EDC' | **Objective II**: To evaluate the operational benefits and perceived impact of DHTs on key clinical trial outcomes, including patient recruitment, retention, data collection, and trial efficiency. |
| | | | **PIR1-**<br>"helpful in terms of paperless approach, the paperless concept so in a way it's good for the environment sustainability"<br><br>"Digital platforms which help us to monitor adverse events for the patients. So some studies like for example like a study where we have been, especially for patients with diabetes where we are what IMP We do have a platform | |

| | | | | |
|---|---|---|---|---|
| | | | **PIN3**<br><br>Data is transmitted in real-time and helpful in detecting any protocol deviations<br><br>These tools reduce manual errors as patients' data is automatically detected by devices and is recorded<br><br>DHT tools have had a positive effect on patient retention. The features like mobile reminders, remote consultations and simplified data entry through this app have helped patients to remain engaged throughout the study.<br><br>Reduce drop out rates | |
| **3. Barriers to Adoption** | i) Patient-related challenges<br>ii) Infrastructure related challenge<br>iii) Technical challenges<br>iv) Data integration | • Digital Literacy<br>• Older patients<br>• Younger generation<br>• Disease<br>• Alzheimer's<br>• Technical issues<br>• Software issues<br>• Language barrier<br>• Rural area<br>• Digital divide<br>• Technology<br>• Integration with existing platforms<br>• Data privacy | **PIN1-"**"Older adults felt unsure how to use the device." "Patients worry about making mistakes on the app." "Internet issues in rural areas. "Sometimes syncing fails due to no Wi-Fi."<br><br>**PIR1-**<br>"elderly patients find technology very difficult. And also for certain trials for dementia conditions like dementia or Alzheimer's"<br><br>"there could be some problems or issues with the technology"<br><br>**PIN2- "**people from lower income background don't have technology access"<br><br>"Some prefer face-to -face consultations rather than remote tele visits"<br><br>"People from rural areas not comfortable with apps, they don't understand the English interfaces"<br><br>"Faces issues with integration of sponsor platforms into hospital system"<br>Some people worry about data privacy and hesitate the use of devices | **Objective III:** To identify and analyse the key challenges that hinder the adoption of DHTs in DCTs across both regions |

| | | | | |
|---|---|---|---|---|
| | | | **PIR2-** older generation finds it difficult to adapt to technology, so we involve carers<br>We faced technical issues that delayed process, the platform stopped working suddenly | |
| | | | **PIN3**<br>Biggest challenge I faced is Data integration. We often have to work with the data from various sources, wearables, mobile apps, and telehealth platform that uses different formats and synchronization schedules.<br><br>So, integrating this data into our central EDC system without losing the quality and context requires some effort<br><br>Another issue is data completeness. Like for example, if a patient forgets to sync their wearable devices or loses their connectivity, we may see gaps in the data stream that can impact analysis. So, in those cases, we have to coordinate with the site staff to follow up with the patient to resolve these issues. | |
| **4. Addressing the key Barriers** | i) Patient training<br>ii) Messages and alerts<br>iii) Testing digital Platforms<br>ii) Seek family and caregiver helps | • Training,<br>• Notification<br>• Alerts<br>• Email remainders<br>• Flow chart<br>• Testing environment<br>• Family<br>• Caregiver | **PIN1-**"“train the older generation people that how to use the technology so that once we give that training to them”<br>“flowchart created for them to understand what's the basic of the clinical trials"<br>“ Testing platforms and apps before using into trials” | **Objective III:**<br>To identify and analyse the key challenges that hinder the adoption of DHTs in DCTs across both regions |
| | | | **PIR1-**<br>“we mitigate these issues is that we try to seek the help of the caregivers.<br>Or maybe it could be the son or daughter or husband” | |
| | | | **PIN2**<br>Conducting training before trial staff | |
| | | | **PIR2**<br>Conducting training and giving alerts and reminders for missed reading | |

| | | | | |
|---|---|---|---|---|
| | | | **PIN3-** providing onboarding support, step-by -step guidance | |
| **5. Regulatory and Data security considerations** | i) Informed Consent<br>ii) Data Encryption<br>iii)Data anonymization | • Informed consent<br>• GDPR | **PIN1-**""All data is encrypted and anonymized per regulation"<br>"India's framework is evolving."<br>**PIR1-"**usually all these systems are highly password protected"<br>**PIN2**<br>-India's framework is developing especially regarding data protection<br>**PIR2-** regulations are adaptive to growing technology<br>**PIN3-** provide clearer guidelines to support the DHT adoption | **Objective III:** To identify and analyse the key challenges that hinder the adoption of DHTs in DCTs across both regions<br><br>**Objective VI:** To provide actionable recommendations for CROs, sponsors, and regulators to optimize the use of DHTs in DCTs. |
| **6. Role of CROs** | i)Selection and testing of Platforms<br>ii) Site staff training<br>iii) Participant onboarding and training<br>iv) Troubleshooting | • Testing<br>• Training | **PIN1-**""they test the platforms, that app is given to the clinical research site"<br>"They help resolve data syncing problems."<br>**PIR1**<br>"if there is any kind of a hassle or issue or delay, we directly call the team and get the things sorted."<br>**PIN2-**DHT tools, were they developed by the sponsors or the contract research organization or they are commercially available technologies<br>**PIR2**<br>Helps troubleshoot the problem , conduct site training, platform selection<br>Helps validating the tools<br>**PIN3**<br>Provide training, troubleshooting issues with apps or platforms | **Objective IV:** To evaluate the role of Contract Research Organizations (CROs) in integrating DHTs into DCTs in India and Ireland. |

| | | | | |
|---|---|---|---|---|
| **7. Future Outlook & Recommendations** | i) Design user friendly apps and tools<br>ii)Automation<br>iii) Advanced Artificial Intelligence<br>iii) Drug development timeline | • User friendly apps<br>• AI<br>• Automation | **PIN1-**"the world is moving towards automation"<br>"We should not go back to paper trials."<br>"AI can drastically reduce trial timelines."<br>"So we are expecting that span of 10 to 15 years can come down to one to five years" | **Objective V**: To identify emerging trends and future expectations for the adoption and expansion of DHTs in decentralized clinical research, based on stakeholder insights from both regions.<br><br>**Objective VI**: To provide actionable recommendations for CROs, sponsors, and regulators to optimize the use of DHTs in DCTs. |
| | | | **PIR1-**<br>"it would be good to have that technical support readily available. Like if you have any issues, it's good to have this technical support readily available so that we can So the end users, if they find that there is an issue so it doesn't<br><br>It doesn't cost lots of time for the staff and patients"<br>"Future should focus on more paperless approach" | |
| | | | **PIN2**<br>"Improve the internet infrastructure, especially for the rural patients because the networking problem issues" | |
| | | | **PIR2**<br>"More technological advancement needed, we shouldn't go back to old models<br>We have seen technology as an enabler not barrier" | |
| | | | **PIN3**<br>Introduce offline capable apps so that patient can record the recording even there is not internet connectivity or face electricity outrages<br><br>Develop more AI and machine learning technology to cleaning and analysing large volume of clinical trial data<br><br>Design apps available in local languages<br><br>Increased collaboration of sponsors and tech providers to design more user-friendly apps | |

## Theme 1- Adoption and Types of Digital Health Technologies(DHTs)

The analysis of participant interviews revealed widespread and increasing adoption of digital health technologies (DHTs) in decentralized clinical trials (DCTs), particularly following the COVID-19 pandemic. Across all five respondents—three from India and two from Ireland—there was clear picture that the pandemic acted as a major catalyst in shifting the clinical research landscape toward digital integration. This finding shows that the Hypothesis I stated in the research is true i.e., COVID-19 accelerated the adoption of DHTs in clinical trials((FDA, 2024; Van, 2021).

Several participants highlighted the transition from traditional, site-based trials to hybrid or partially decentralized models. This shift was supported by the implementation of various DHTs, including electronic data capture (EDC) systems, e-Consent platforms, mobile health apps, telemedicine tools, and remote monitoring devices. For instance, PIR2 remarked, *" over the past three years, there has an increase in the use of digital tools in trials after COVID-19*," emphasizing the transformative role of the pandemic in digital acceleration.

Commonly used DHT platforms:

- Wearable devices were widely used for real-time monitoring of vitals such as blood pressure, heart rate, and activity. PIN1 referenced wearable blood pressure monitors, while PIR2 cited the use of Fitbit and ECG patches.
- Remote monitoring tools, like continuous glucose monitors, were employed in trials involving diabetes, enabling participants to log readings via mobile apps from home **(**PIN3).
- Mobile apps supported symptom tracking, medication adherence. As noted by PIN2, "*We used apps for symptom tracking and also for medication reminders.*"
- Platforms like REDCap, Medidata, and MFine (a telemedicine tool common in India) were cited for virtual consultations and data collection.
- The ECOA (Electronic Clinical Outcome Assessment) platform was used to automatically receive data from wearable devices, streamlining collection and analysis (PIN1).

These findings demonstrate a clear trend of DHT integration across trial functions—from recruitment and consent to data capture and safety monitoring. The recurring use of such

technologies suggests a growing confidence among clinical teams and participants in the effectiveness and utility of DHTs in trial execution.

## Theme 2: Benefits of DHTs in Decentralized Clinical Trials

The integration of digital health technologies (DHTs) in decentralized clinical trials (DCTs) has yielded numerous benefits across various trial functions. One of the most frequently mentioned benefits was improved patient recruitment and retention. As PIN1 stated, "*Patient recruitment has improved now*," attributing it to the convenience offered by digital platforms. Tools like mobile apps, wearable devices, and telemedicine consultations have increased accessibility, especially for patients in remote or underserved regions. PIN2 emphasized that DHTs allow sites to "*reach patients who live in remote areas or have mobility limitations.*"

Real-time data collection and remote monitoring enhanced data quality and protocol adherence. Several participants mentioned that devices like continuous glucose monitors or wearable ECG patches transmit information immediately, enabling quicker detection of safety signals and adverse drug reactions (ADRs). For example, PIR1 described a platform specifically designed to track hypoglycaemic events in diabetic patients, while PIN3 noted that "*data is transmitted in real-time and helpful in detecting any protocol deviations.*"

DHTs also contributed to enhanced patient engagement and adherence through features like digital reminders, symptom tracking, and medication adherence tools (PIN3). Another theme was reduction in manual workload and paper usage, leading to more efficient workflows and environmental sustainability. PIN1 mentioned a shift toward a "*paperless approach*," with direct data entry into EDC platforms, and PIR1 added that this digital shift is beneficial for "*environmental sustainability*."

Participants also valued the reduction in site visits. PIR2 shared that follow-up through video or phone reduced the need for physical presence, which increased patient convenience and reduced site burden.

Overall, the qualitative evidence highlights that DHTs enhance the overall efficiency of digital tools by improving patient recruitment, patient engagement, and data collection. These findings strongly support Objectives II of the study i.e., the benefits of using DHTs in clinical trials and also confirm that Hypothesis II (i.e., DHTs improve patient recruitment, retention, and data quality in decentralized clinical trials) is true.

## Theme 3: Barriers to Adoption of DHTs

Despite the benefits of digital health technologies (DHTs), interview participants highlighted several barriers that hinder their widespread adoption in decentralized clinical trials (DCTs). A common concern was digital literacy, particularly among older adults and those in rural or low-income areas. As PIN1 noted, "*Older adults felt unsure how to use the device,*" and PIN2 added that many patients struggle with English-based interfaces or prefer face-to-face consultations.

Infrastructure challenges were also prominent, with poor internet connectivity, lack of access to devices, and frequent technical glitches mentioned. PIR2 shared that the platform "*stopped working suddenly,*" delaying trial processes. In addition, PIN2 reported issues with integrating sponsor platforms into hospital systems, and PIN3 described the difficulty of merging data from wearables, mobile apps, and telehealth into central EDC systems, affecting data completeness and quality.

Concerns around data privacy and patient hesitancy to share personal information further limited adoption. These challenges highlight the need for better training, infrastructure, and system integration to support the effective use of DHTs in clinical trials.

## Theme 4: Addressing the Key Barriers to DHT Adoption

Participants shared several strategies to overcome adoption challenges of digital health technologies (DHTs), particularly among older or less tech-savvy participants. A common approach was patient training before and during the trial, including step-by-step guidance, visual aids like flowcharts, and onboarding sessions. PIN1 noted, "*We trained older generation people... and used flowcharts to explain how the device works.*"

Caregiver involvement was also important, with PIR1 highlighting that caregivers often support elderly patients during digital engagement. Additionally, the use of reminders and alerts—via messages, app notifications, or emails—was cited as helpful in improving adherence. Respondents also stressed the importance of testing platforms in controlled environments before launching them in live trials. These practices reflect proactive solutions to the challenges associated with implementation of DHTs in clinical trials.

## Theme 5: Regulatory and Data Security Considerations

While most participants recognized the importance of data security, there was a noted difference in regulatory maturity between Ireland and India. Respondents in Ireland referenced compliance with GDPR, encrypted systems, and informed consent protocols. PIR1 stated, "*All data is encrypted and anonymized per regulation.*"

However, Indian professionals noted that the regulatory framework is still evolving, especially regarding data protection and guidelines for DHTs. Despite this, both groups emphasized adherence to informed consent and secure data storage, reflecting awareness of ethical requirements. These insights align with Objectives III and VI, which examine regulatory and privacy-related challenges.

## Theme 6: Role of Contract Research Organizations (CROs)

All participants acknowledged the critical role of CROs in implementing DHTs in decentralized trials. Their responsibilities included selecting and validating platforms, training site staff, onboarding participants, and providing technical troubleshooting. PIN1 shared, "*They test the platforms and hand them over to the research site.*" Similarly, PIR2 emphasized that CROs were "*central in resolving issues and guiding platform use.*"

CROs served as intermediaries between sponsors, tech vendors, and research sites, ensuring smooth DHT integration. These findings reinforce the operational importance of CROs under Objective IV.

## Theme 7: Future Outlook and Recommendations

Interviewees were optimistic about the future of DHTs, envisioning trials becoming more automated, AI-driven, and patient-friendly. PIN1 highlighted, "*With automation and AI, we expect drug development timelines to reduce from 10–15 years to just 5.*" Respondents also stressed the need to design user-friendly apps, especially for patients with low literacy or limited tech access.

Other key suggestions included introducing offline-capable apps, improving internet infrastructure, and providing multilingual interfaces. Emphasis was placed on sponsor–tech

provider collaboration to build inclusive tools. These forward-looking views support Objectives V and VI, addressing stakeholder expectations and areas for system improvement.

# 5 CONCLUSIONS AND RECOMMENDATIONS

**Research Conclusions**

This study set out to explore the adoption, opportunities, and challenges of Digital Health Technologies (DHTs) in Decentralized Clinical Trials (DCTs) across India and Ireland. Through a mixed-methods approach comprising quantitative surveys and qualitative interviews with clinical research professionals, the following research conclusions have been drawn:

**Current Level and Types of DHT Adoption**

The study reveals a notable disparity in DHT adoption between India and Ireland. Irish organizations demonstrate higher levels of DHT integration, with many reporting either advanced or fully integrated use of technologies like telemedicine, e-consent platforms, wearable devices, and remote monitoring tools. Tools such as Zoom for Healthcare, Patients Know Best, and Epic Telehealth are widely used in Ireland, reflecting digital maturity. In contrast, India exhibits more fragmented and limited adoption, with nearly one-third of respondents reporting no DHT use. However, there are promising developments—such as e-Sanjeevani and custom sponsor-developed apps—indicating early-stage adoption in select institutions. Indian respondents also showed slightly higher usage of AI-based monitoring tools, suggesting emerging interest in next-generation DHTs despite broader infrastructural gaps.

**Operational Benefits and Impact of DHTs**

Across both countries, respondents consistently affirmed the operational benefits of DHTs in decentralized clinical trials. Key gains included real-time data collection, reduced administrative burden, improved patient retention, and higher trial efficiency. Research nurses

and coordinators emphasized that automated reminders, digital symptom tracking, and remote follow-ups helped reduce missed visits and dropout rates. Interviewees from India specifically highlighted how digital tools enhanced engagement in remote or underserved populations. Meanwhile, Irish respondents reported smoother workflows, with high uptake of mobile health apps, wearable integration, and eConsent platforms improving regulatory compliance and onboarding speed. The respondents also highlighted the role of DHTs in improving patient-centricity and reducing site visit burdens.

**Challenges Hindering DHT Adoption**

The challenges to DHT adoption varied between regions but were significant in both. In India, key barriers included limited digital literacy, lack of robust internet connectivity in rural areas, and some people in India finds difficulty in navigating the English app interfaces due to language variability. Infrastructure gaps and cost-related concerns—such as device affordability and data plans—were also prevalent. Regulatory ambiguity, particularly around data privacy and e-consent protocols, further discouraged broader uptake. In Ireland, the primary barriers were workforce readiness, technical integration challenges, and compliance with GDPR. Both countries cited technical malfunctions, data synchronization issues, and device accuracy as recurring problems. Importantly, research nurses identified that older adults or patients with disabilities often faced usability issues, indicating the need for inclusive design and targeted training.

**Role of Contract Research Organizations (CROs)**

The role of CROs emerged as critical to DHT implementation, particularly in Ireland where they are consistently involved in technology selection, regulatory support, participant training, and data management. Irish stakeholders reported high confidence in CRO capabilities, with over 96% acknowledging their role in analytics and tech support. In India, CRO engagement was more variable. While some respondents highlighted strong partnerships, 18% reported minimal involvement, especially in participant-facing roles. Interviews confirmed that in both countries, CROs play a central role in testing platforms, training site teams, and ensuring protocol compliance. Their effectiveness directly influences trial timelines, regulatory

approval, and DHT usability. Thus, strengthening CRO capacity and standardizing their involvement remains essential for expanding DHT use in decentralized trials.

### Emerging Trends and Future Outlook

Both survey data and interviews point toward a future where hybrid trials—combining on-site and decentralized elements—will dominate. Stakeholders foresee broader adoption of AI, machine learning, blockchain, and advanced wearable sensors. Ireland's ecosystem is well-positioned to lead in digital transformation, while India's focus is on expanding DHTs to rural and marginalized populations. Respondents emphasized the importance of real-time safety monitoring, remote inclusivity, and faster patient recruitment as future benefits. There is optimism that automation and mobile-based platforms will reduce trial costs and improve drug development timelines. However, this digital growth must be accompanied by stronger data protection laws, interoperability standards, and capacity building initiatives, especially in low-resource settings.

These findings directly address the study's objectives by illustrating the regional contrasts, identifying the perceived benefits and barriers, and evaluating the roles of stakeholders in advancing DCTs.

### Strategic Conclusions

Based on the insights derived from this research, several strategic conclusions can be drawn:

- Localized Approaches are Essential**:** Successful implementation of DHTs requires context-specific strategies. In India, overcoming infrastructural and educational challenges must take precedence, while Ireland should prioritize system integration and regulatory adaptation.
- Hybrid Trials Are the Future**:** Stakeholders overwhelmingly indicated a preference for hybrid models, blending digital tools with traditional methods. This reflects the current readiness levels and the varying comfort zones of patients and trial staff.
- Patient-Centric Design is Critical**:** To ensure higher patient engagement and retention, DHTs must be designed with user experience in mind. This includes intuitive interfaces, multilingual options, and features that accommodate varying literacy levels.

- Trust and Data Security Must be Strengthened**:** Patients' willingness to participate in DCTs hinges on confidence in data security. Strengthening encryption protocols, ensuring transparency in data handling, and aligning with global standards like GDPR are essential.
- Stakeholder Collaboration Drives Success**:** Coordinated efforts among sponsors, CROs, regulators, and technology developers are crucial for successful DHT adoption. Collaborative frameworks ensure that innovations are scalable, compliant, and tailored to stakeholder needs.

**Recommendations**

Drawing from the above conclusions, the following actionable recommendations are proposed to facilitate wider and more effective use of DHTs in DCTs:

1. **Infrastructure Investment**
    - Improve rural internet connectivity and provide subsidies for digital devices used in clinical trials especially in developing countries like India.
    - Encourage government initiatives to integrate telecommunication infrastructure with healthcare delivery systems.
2. **Digital Literacy and Capacity Building**
    - Launch training programs tailored to both patients and professionals. Include modules on device usage, data entry, and security protocols.
    - Develop culturally sensitive, multilingual training materials that consider regional variations in literacy.
3. **Patient-Centered Technology Design**
    - Involve end-users in the design phase of DHT tools to ensure usability.
    - Incorporate features like voice-guided navigation, offline modes, and auto-reminders.
4. **Regulatory Harmonization and Clarity**
    - India should develop specific guidelines for DHT implementation in line with global standards.
    - Encourage ethical review boards to adopt fast-track approval mechanisms for trials using pre-validated DHTs.

5. **Strengthen CRO Involvement**
    - Standardize CRO responsibilities in supporting digital trial infrastructure.
    - Promote partnerships between CROs, tech vendors, and public institutions to scale successful pilot models.
6. **Public Awareness and Community Engagement**
    - Use mass media and grassroots campaigns to increase awareness about the safety and benefits of DHTs.
    - Highlight successful case studies to build trust and normalize participation in digital trials.
7. **Incentivize Innovation and Public-Private Collaboration**
    - Provide government incentives for start-ups developing DHT platforms.
8. **Improve Data Governance Practices**
    - Introduce mandatory data anonymization standards and audit mechanisms.
    - Ensure all platforms used in trials are compliant with international data protection regulations.

**Limitations of the Study**

While the study provides valuable insights, it is not without limitations:

- The use of self-reported survey data may introduce response bias.
- The sample was limited to clinical research professionals, excluding broader stakeholder views such as patients, regulators, and tech developers.
- The focus on India and Ireland limits the generalizability of findings to other regions with different health systems and regulatory landscapes.
- The cross-sectional nature of the data collection does not allow for evaluation of long-term impacts or evolving trends.

**Contributions of the Research**

Despite the limitations, the study makes several key contributions:

- It provides a comparative perspective on DHT adoption in two distinct regulatory and infrastructural contexts.

- It enriches existing literature by integrating both quantitative and qualitative insights to provide a holistic view.
- It offers practical recommendations grounded in empirical evidence for various stakeholders involved in DCTs.
- It emphasizes the role of human-centered design, infrastructure, and regulatory policy in enabling digital innovation.

**Suggestions for Future Research**

This study opens several avenues for future exploration:

- **Patient Perspectives:** Incorporate qualitative research focusing on patient experiences and attitudes towards DHTs.
- **Longitudinal Studies:** Track the implementation and outcomes of DHTs over extended periods to assess sustainability.
- **Cross-Regional Studies:** Compare DHT adoption across more diverse geographic and economic contexts, including low- and middle-income countries.
- **Policy Impact Research:** Evaluate how changes in regulatory frameworks influence DHT adoption rates and trial outcomes.

**Final Reflection**

Conducting this dissertation has provided me with a deep appreciation for the complexity of digital transformation in healthcare. It has highlighted that while technology can drive efficiencies and widen access, its success depends heavily on infrastructure, policy, user acceptance, and stakeholder collaboration. This journey has not only honed my academic and analytical capabilities but also strengthened my resolve to contribute meaningfully to the evolution of patient-centric, technology-enabled clinical research. Through this work, I hope to inspire further innovation and inclusive practices in the global health research ecosystem.

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# 7 APPENDICES

## 7.1 APPENDIX 1- ONLINE SURVEY QUESTIONS

# Opportunities and Challenges in Implementing Digital Health Technologies in Decentralised Clinical Trials: A Comparative Analysis of India and Ireland

Dear Participant,

I hope you are doing well.

My name is Gifty Peter, and I am currently pursuing an MSc in Pharmaceutical Business and Technology at Griffith College, Dublin, Ireland. As part of my academic dissertation, I am conducting a survey to explore the opportunities and challenges associated with implementing Digital Health Technologies in Decentralized Clinical Trials in India and Ireland. Given your expertise in this field, your insights would be invaluable to this research.

The survey will take approximately 5–7 minutes to complete, and participation is entirely voluntary—you may choose to withdraw at any time without any consequences. All responses will remain anonymous and confidential, used solely for research purposes. The data will be securely stored in an electronic format and retained for two years before permanent deletion, in full compliance with GDPR guidelines. Access will be restricted to myself (the researcher) and relevant academic staff at Griffith College.

Your time and valuable input are greatly appreciated.

**Sincerely,**
Gifty Peter

By ticking the box below, you confirm that you have read and understood the purpose of this study. This study aims to gather responses from potential participants regarding the opportunities and challenges in implementing digital health technologies in decentralized clinical trials, with a comparative focus on India and Ireland. *

I confirm that I have thoroughly read and understood the purpose of the study.

By ticking the box below you are giving your consent to participate in this survey, understanding that your responses will be used in the dissertation mentioned above *

I hereby consent to participate in this survey and I understand that my responses will contribute to the finishing of the dissertation mentioned above
No, I do not wish to participate in the survey

## Demographics

*(All participants answer these questions)*

1. What is your current country of residence?*

India
Ireland
Other:

2. What is your gender?*

Male
Female
Other:

3.What is your age group ?*

18-25
25-35
35-45
45-55

4. What is your level of education?*

Doctorate Degree
Master's Degree
Bachelor's Degree
Advance Diploma
Certificate/Diploma

5. What is your current role? *

Clinical Research Associate (CRA)
Clinical Operations Manager
Clinical Data Manager
Clinical Trial Manager
Clinical Trial Coordinator
Principle Investigator
Sub-investigator
Research Nurse
Other:
clinical data coordinator

6. How many years of experience do you have in clinical research?*

Less than 1 year
1-3 years
4-7 years
More than 7 years

For Clinical Research Associates/Clinical operations Managers/Clinical Data Managers/Clinical Trial Coordinators /Investigators

1. What percentage of your clinical trials in your organization use Digital Health Technologies?

*

1%-25%
26%-50%
**51%-75%**
76%-100%

2. How would you rate your organization's overall adoption of Digital Health Technologies (DHTs) in clinical trials ?

*

Not adopted
Early stages of adoption
**Moderate adoption**
Advanced adoption
Fully integrated

3. How has the COVID-19 pandemic influenced your organization's adoption of DHTs in clinical trials?

*

Significantly accelerated adoption
Moderately accelerated adoption
Slowed adoption
**No change**

4. Which Digital Health Technologies (DHTs) does your organization frequently use for decentralized clinical trials (DCTs) ? (*Select all that apply)*

*

Telemedicine Platforms
e-Consent Platforms
Remote Monitoring Devices
Wearable Devices
Mobile health apps
AI-based Patient Monitoring Tools
**Electronic Health records (EHRs)**
Blockchain for Data Security
None
Other:

5. Which types of Telemedicine services does your organization currently use? (*Select all that apply)*

*

Store-and-forward (asynchronous)
Real-time (synchronous) video consultations

Teleconsultation via phone/audio only
None

Teleconsultation via phone/audio only
None

7. For Remote Monitoring Devices, which types does your organisation most commonly use in clinical trials? *(Select all that apply)*

*

Continuous glucose monitors
Fitness trackers
Smartwatches
Blood pressure monitoring devices
Pulse oximeters
ECG monitors
Sleep trackers
Smart Inhalers
Digital patches and biosensors
None
Other:

8. Which of the following Remote Monitoring Devices does your organization frequently use in clinical trials? *(select all that apply)*

*

Fitbit
Apple Watch
Garmin
Philips Biosensors
Medtronic LINQ II
Abbott FreeStyle Libre
Biotelemetry patches
None
Other:

9. What data does your organisation collect from participants using remote monitoring devices? *(select all that apply)**

Heart rate
Physical activity
Blood glucose
Sleep patterns
Medication adherence
None
Other:

10. Which types of Mobile Health apps does your organization use in clinical trials?

*

Patient-reported outcome apps
Medication adherence apps

*

Patient-reported outcome apps
Medication adherence apps
Symptom tracking apps
Wearable integration apps
None
Other:

11. Which of the following e-Consent platforms does your organisation have you used? *(Select all that apply)*

*

Veeva eConsent
Medidata Rave eConsent
DocuSign
TrialConsent
CliniOps eConsent
Florence Healthcare
None
Other:

12. How does e-Consent platforms improve trial efficiency? *(Select all that apply)* *

Faster consent process
Broader patient reach (e.g., rural areas)
Reduced paperwork
Improved compliance with regulatory requirements
Improve operational efficiency by reducing administrative burden
Makes approval process faster
Other:

13. What are the main opportunities for using telemedicine, remote monitoring devices, and mobile health apps in clinical trials? *(Select all that apply)*

*

Real-time data collection
Improved patient engagement
Improved patient recruitment
Better patient outcomes
Increased convenience for patients
Reduced site visits for participants
Improved trial accessibility
Enhanced communication between patients and trial coordinators
Better data accuracy through remote monitoring
Real-time feedback and alerts
Increased trial efficiency

Increased cost savings

Increased cost savings
More convenient to sponsor
Other:

14. What are the key challenges of using Digital Health technologies in clinical trials? *(Select all that apply)**

Comparative lack of standardized regulatory guidelines
Data privacy concerns
Technical issues
Patient-related challenges
Ensuring data reliability and quality
Data collection challenges
Lack of training or expertise in DHTs
Resistance from clinical staff
Increased workload for clinical staff
No challenges
Other:

15. What technical challenges has your organisation faced during the implementation of Digital Health technologies in Clinical Trials ? *(Select all that apply)*

*

Difficulty integrating digital tools with existing system
Lack of robust internet connectivity in rural or remote areas
Software malfunctions like bugs or technical glitches in telemedicine platforms, mobile apps, or monitoring tools
Challenges in synching data from multiple devices or platforms
Inability of digital health platforms to work seamlessly with other systems or devices
Concerns about device accuracy and reliability on collected data
High maintenance cost
Lack of expertise or resources to troubleshoot technical issues
Difficulty in handling large volumes of data generated by DHTs
No challenges
Other:

16. What patient-related challenges has your organization faced during the implementation of Digital Health Technologies (DHTs) in clinical trials? *(Select all that apply)**

Limited digital literacy
Patients feel uncomfortable or hesitant to use wearables or other monitoring tools
Patients in rural or underserved areas face connectivity issues
Patients prefer traditional methods and are reluctant to adopt digital tools
Patients find it challenging to follow guidelines for using DHTs
Patients worry about the security of their health data
Patients with disabilities or chronic conditions may find it hard to use certain devices

Patients from diverse backgrounds may face challenges with language or culturally inappropriate designs.
Patients experience problems with device setup, connectivity, or functionality
No challenges
Other:

Patients from diverse backgrounds may face challenges with language or culturally inappropriate designs.
Patients experience problems with device setup, connectivity, or functionality
No challenges
Other:

**17. Have you encountered any challenges related to data security or privacy concerns while using DHTs? If any select all that apply.**

*

Unauthorized access to patient data
Accidental disclosure of sensitive information
Data breaches from external cyber attacks
Misuse of data by authorized personnel
Lack of patient consent for data sharing
Systemic data flows to third parties without patient knowledge
Insufficient data protection measures for electronic health records
Difficulty in complying with evolving data protection regulations
Concerns about data storage and retention practices
**No, I have not encountered any data security or privacy issues**
Other:

**18. What is your satisfaction level with the current regulatory guidelines for DHTs in your country? *(Select all that apply)***

*

Current regulations are clear and easy to understand
The guidelines are adaptable to new and innovative DHTs
The regulations clearly address data security and patient privacy
Guidelines supports the use of DHTs in decentralized trials
Regulations are updated regularly to keep pace with technological advancements
The guidelines are effectively enforced and widely followed
The current regulations are satisfactory but need to be updated to address the ethical and privacy concerns
**The guidelines are not adaptable to new and innovative DHTs**
The current regulations are inadequate and does not address the challenges
Other:

**19. How involved are Contract Research Organizations (CROs) in the implementation of DHTs in decentralized clinical trials in your experience?**

*

**Very involved**
Somewhat involved
Neutral

Not very involved
Not involved at all

**20.Which of the following areas do CROs typically support in relation to DHTs in your trials? *(Select all that apply)***

Not very involved
Not involved at all

20.Which of the following areas do CROs typically support in relation to DHTs in your trials? *(Select all that apply)*

Selection and integration of DHT tools
Regulatory compliance and submissions
Participant onboarding and training
Data management and analytics
Technical support and troubleshooting
None of the above

21. What do you think is the future of DHTs in decentralized clinical trials? *(Select all that apply)*

*

DHTs will become the standard for all clinical trials.
DHTs will be used in combination with traditional methods (hybrid trials).
DHTs will remain niche and only used in specific cases.
DHTs will face too many barriers to become widely adopted.
Other:

22. What emerging technologies do you believe will have the biggest impact on clinical trials in the next 5 years? *(Select all that apply)*

*

Artificial Intelligence (AI) and Machine Learning (ML)
Blockchain for data security
Advanced wearable devices
Virtual and Augmented Reality (VR/AR)
Other:

23. What measures do you think could improve the patient engagement and trust in telemedicine and remote monitoring devices ? *(Select all that apply)**

Educational campaigns to increase awareness and understanding of digital health tools.
Creating user-friendly interfaces by simplifying the design of apps and devices for ease of use.
Providing training for patients on how to use telemedicine and remote monitoring tools.
Providing personalized support by offering one-on-one assistance for patients unfamiliar with technology.
Providing feedback mechanisms to patients to share their experiences and suggest improvements.
Other:

24. What recommendations would you suggest for governments to improve the adoption of digital health technologies in clinical trials and healthcare? *(Select all that*

24. What recommendations would you suggest for governments to improve the adoption of digital health technologies in clinical trials and healthcare? *(Select all that apply)**

Provide clear guidelines for the use of digital health tools in clinical trials.
Offering grants or subsidies for organizations adopting digital health technologies.
Investing in internet connectivity and digital infrastructure, especially in rural areas.
Developing Public-private partnerships by collaborating with tech companies to develop digital health solutions.
Conducting training and awareness programs to improve digital literacy among healthcare providers and patients.
Strengthening laws to protect patient data and ensure compliance (e.g., GDPR, DPDP Act).
Other:

25. What other recommendations would you give to regulators, sponsors, and CROs to improve the adoption of DHTs in decentralized clinical trials?

**For Research Nurses**

1. Which Digital health tools have you encountered within your professional working environment? *(Select all that apply)**

Telemedicine platforms
Wearable devices (e.g., Fitbit, Apple Watch)
Remote monitoring tools (e.g., blood pressure cuffs, glucose monitors)
Mobile health apps (e.g., for patient-reported outcomes)
e-Consent platforms
AI-driven analytics tools
Other:

2. How would you rate the effectiveness of Digital Health technologies (DHTs) in improving clinical trial processes? *(1 = Not effective, 2= Somewhat effective , 3=Neutral ,4= Effective 5 = Very effective)**

Patient recruitment
Patient retention
Data collection and accuracy
Patient engagement
Overall trial efficiency
Patient recruitment
Patient retention
Data collection and accuracy
Patient engagement
Overall trial efficiency

3. How do patients generally respond to the use of DHTs?*

Very positively
Somewhat positively
Neutral

Somewhat negatively
Very negatively

4.Do patients feel comfortable while using digital tools (e.g., mobile apps, wearables like smart watches, fitness trackers, video consultations) to monitor their health ?

*

Somewhat negatively
Very negatively

**4.Do patients feel comfortable while using digital tools (e.g., mobile apps, wearables like smart watches, fitness trackers, video consultations) to monitor their health ?**

*

Yes, very comfortable
Somewhat comfortable
Neutral
Not very comfortable
Not comfortable at all

**5. How do you support patients in using DHTs? *(Select all that apply)****

Providing training sessions
Offering written or video instructions
Assigning a dedicated support person
Using simpler or more user-friendly tools
Regular follow-ups to address issues
Other:

**6. Do you think more people would participate in clinical trials if they were conducted remotely using digital health technologies?***

Yes
No
Maybe

**7.What challenges do you think might prevent people from participating in these type of clinical trials? *(Select all that apply)***

*

Lack of awareness about clinical trials/Decentralized clinical trials
Concerns about potential side effects
Time commitment
Difficulty understanding medical jargon
Lack of trust in pharmaceutical companies
Lack of awareness of Digital Health technologies(DHTs) like remote monitoring devices, wearables, etc
Concerns about data privacy and security
Limited access to internet or required technology
Other:

**8.What challenges have you faced in managing data collected through DHTs? *(Select all that apply)****

Data synchronization issues
Ensuring data accuracy and reliability
Data privacy and security concerns
Handling large volumes of data
Integrating data with existing systems (e.g., Electronic Health Records, Electronic Data Capture)

Ensuring data accuracy and reliability
Data privacy and security concerns
Handling large volumes of data
Integrating data with existing systems (e.g., Electronic Health Records, Electronic Data Capture)
Not Sure
Other:

9.What operational challenges have you faced when using DHTs ? *(Select all that apply)*

*

Technical issues with devices or platforms
Difficulty integrating DHTs with existing systems
Increased workload for staff
Resistance from colleagues or patients
High implementation or maintenance costs
Other:

10. How do regulatory requirements impact the use of DHTs ?

*

They significantly delay or hinder adoption.
They somewhat delay or hinder adoption.
They have no impact.
They facilitate adoption.
Not sure

11. Have you received adequate training on using DHTs?*

- Yes, very adequate
- Somewhat adequate
- Neutral
- Not very adequate
- Not at all adequate

13. How do you rate the digital infrastructure in your country?

1

2

3

4

5

13. What improvements would you recommend to enhance the use of DHTs in clinical trials? *(Open-ended)*

**Thank You for Your Participation!**

## 7.2 APPENDIX 2- INTERVIEW QUESTIONS

### Section 1: Introduction and Background

1. Can you briefly describe your role and experience in clinical trials, particularly in clinical trials or digital health technologies (DHTs)?
   - How long have you been working in this field?
   - Have you been involved in trials that use DHTs? If yes, which ones?

### Section 2: Adoption and Impact of DHTs

2. What digital health technologies (e.g., telemedicine, wearables, mobile apps) have you used or observed in decentralized trials?
   - Which ones do you find most effective?
   - Have these technologies improved trial processes (e.g., recruitment, retention, data collection)?
3. What are the biggest **benefits and challenges** of using DHTs in decentralized trials?
   - Do they improve patient engagement?
   - What obstacles (e.g., training, usability, compliance) have you encountered?

### Section 3: Patient Recruitment and Retention

6. How has the use of DHTs affected patient recruitment and retention?
   - Are trials becoming more accessible to diverse populations?
   - What strategies work best to keep participants engaged?
7. What are the main barriers patients face when using DHTs in trials?
   - Are there concerns about digital literacy, trust, or usability?
   - How do you overcome these challenges?
8. How do participants respond to the adoption of DHTs like telemedicine, wearbles in clinical trials ?

### Section 5: Data Collection, Security, and CROs

8. How do DHTs impact data collection and quality in decentralized trials?
   - Have they improved data accuracy and completeness?
   - What challenges do you face in managing digital trial data?
9. How do you ensure the privacy and security of patient data when using DHTs?
   - What measures (e.g., encryption, access controls) help protect data? ○ Are there concerns about regulatory compliance?
10. What role do Contract Research Organizations (CROs) play in supporting DHT adoption?

- How do they assist sponsors and investigators?
- Are there any key challenges CROs face in this area?

### Section 6: Future Opportunities and Recommendations

11. What are the biggest opportunities for DHTs in decentralized trials?

- Do you see emerging technologies (e.g., AI, blockchain) shaping future trials?
- What improvements would help expand DHT adoption?

12. What recommendations would you give to improve DHT implementation?

- Are changes needed in **regulations, infrastructure, or training**?
- How can DHTs be made more accessible to all participants, including those in underserved areas?

### Section 7: Closing

13. Is there anything else you'd like to share about your experiences with DHTs in decentralized trials?

- Any key challenges or successes you'd like to highlight?
- Final thoughts or recommendations for researchers or policymakers?

## 7.3 APPENDIX 3- INFORMED CONSENT FORM


**Consent to take part in research**

**Title of the Study:**

Opportunities and Challenges in Implementing Digital Health Technologies in Decentralised Clinical Trials: A Comparative Analysis of India and Ireland

- I [*insert participant name*] voluntarily agree to participate in this research study
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
- I understand that participation involves a 20-30 minute one-to-one interview with a set of list of questions.
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I agree to my interview being audio-recorded
- I understand that disguised extracts from my interview may be quoted in in the dissertation, and if published in conference presentations, published papers, ejournals, or in Griffth College Dublin library.
- I understand that I will adhere to all of the codes of conduct and employee confidentiality for my company and there is no expectation to breach these by partaking in this research.

- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be retained will be retained on the researcher's password-protected laptop until May 2027 or if published up to August 2032.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for up to two years.
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

**Researcher Details**

Name : Gifty Peter

Degree Programme: MSc in Pharmaceutical Business and Technology

College Details: Griffith College, Dublin

Contact number: 08922602020

Contact mail: gifty.peter@student.griffith.ie

***Signature of participant***

Signature of research participant

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

***Signature of researcher***

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

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

Signature of researcher

## 7.4 PARTICIPATION INFORMATION LEAFLET

GRIFFITH COLLEGE

**Participant Information Letter**

**Title of the Study:**

**Opportunities and Challenges in Implementing Digital Health Technologies in Decentralized Clinical Trials: A Comparative Analysis of India and Ireland**

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. 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

My name is Gifty Peter, and I am a student at Griffith College Dublin, where I am undertaking a Master's in Pharmaceutical Business and Technology. This research forms part of the final dissertation module, which leads to a Level 9 MSc qualification. This dissertation focuses on the implementation of digital health technologies (DHTs) in decentralized clinical trials (DCTs). The study aims to explore the opportunities and challenges of using DHTs in DCTs, with a comparative analysis of India and Ireland. Specifically, the research will examine:

- The adoption of DHTs in DCTs.
- The regulatory frameworks governing DHTs in both countries.
- The impact of digital tools on patient recruitment, retention, and data collection.
- The role of Contract Research Organizations (CROs) in facilitating DHT adoption.

The goal of this study is to provide actionable recommendations for stakeholders to optimize the use of DHTs in DCTs, ultimately improving the efficiency and accessibility of clinical trials.

WHAT WOULD TAKING PART INVOLVE?

You will be asked to participate in a one-to-one interview with the researcher, Gifty Peter, which will last approximately 15-20 minutes but no longer than 30 minutes. The interview can be conducted in person, by telephone, or online using Teams/Zoom.

The interview will be audio-recorded to facilitate accurate note-taking for transcription. The information collected will be coded and used anonymously in the analysis and dissertation write-up.

The interview will consist of six main sections, with **2-4 subparts** for each. The same questions will be asked of all participants. These questions will focus on your experiences, knowledge, and perspectives regarding the use of DHTs in DCTs, particularly in the contexts of India and Ireland.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to participate in this research because you fulfill the requirements for participation as you are an expert in your field with experience in clinical trials, digital health technologies, or decentralized clinical trials and you have relevant professional experience in either India or Ireland, or both.Your insights will be invaluable in understanding the opportunities and challenges of implementing DHTs in DCTs.

DO YOU HAVE TO TAKE PART?

Participation is completely voluntary. If you choose not to participate, there will be no adverse consequences. You can also refuse to answer any specific question during the survey or interview and withdraw from the study at any time without providing a reason. If you decide to withdraw, please email me at gifty.peter@student.griffith.ie or at 0892262020

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

There are no significant risks associated with participating in this study. However, as with any research, you may feel that some questions are sensitive. You can skip any question or withdraw at any time. All data will be anonymized to protect your privacy and confidentiality.

Your participation will contribute to research on digital health technologies in decentralized clinical trials, which may help improve the implementation and regulation of such technologies in the future.The findings of this study may inform future policies and practices in clinical research, benefiting patients, researchers, and healthcare systems.

WILL TAKING PART BE CONFIDENTIAL?

All information you provide will be kept strictly confidential and used solely for research purposes. . Confidentiality will only be broken in exceptional cases where there is a serious risk of harm to you or others

You should know that non-anonymised data in the form of signed consent form is collected. Audio recordings are anonymised, these are collected and retained as part of the research process. All data will be stored on a password-protected device and only accessed by the researcher. Data analysis is coded and therefore confidentiality is provided in the data analysis and discussion.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms and original audio recordings will be retained in a password protected laptop stored in a cabinet, whose sole use is by the researcher. It will be stored for 2 years after the dissertation is submitted, expected date of submission is May 2025. If the research is published data will be stored for 4-7 years. Under freedom of information legislation, you are entitled to access the information you have provided at any time

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

All dissertation research projects, and their content will be made accessible in the college library and could potentially be made available in online e-journals or repository.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

If you have any questions or require further information, Please Contact:

**Gifty Peter** (Researcher)
Email: gifty.peter@student.griffith.ie or

**Dr. Munira Derby** (Supervisor) –
Email: derbym@innopharmalabs.com.

THANK YOU