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Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India

Innopharma Faculty of Pharmaceutical Science

Dissertation submitted in partial fulfilment of the requirements for

M.Sc.in Pharmaceutical Business & Technology (QQI)

Submitted by

Abna Sreedhar Vysiapat

Student number – 3156884

Under The Guidance Of

Francesca Rizzarello

Aug 2025

CANDIDATE DECLARATION

I certify that the dissertation titled **Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India** submitted for the degree of MSc in Pharmaceutical Business and Technology is the result of my own work and that where reference is made to the work of others, due acknowledgment is given.

Candidate signature: 

Date: 24/ 08 / 2025

Supervisor Name: Francesca Rizzarello

Supervisor Signature: 

Date: 24/ 08 / 2025

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"Working hard is important, but there's something that matters even more. Believing in yourself."

These words resonate deeply with my journey in completing this dissertation. While hard work has been a constant companion, it was the belief, encouragement, and support of the people around me that truly carried me through this process.

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On a personal note, I owe immense gratitude to my mother, **Mrs. Laly S.V.** whose unwavering love, encouragement, and belief in me have been a source of strength and inspiration. I am equally thankful to my friends here in Ireland and back in India, whose constant motivation and faith in my abilities reminded me to keep moving forward even during challenging times.

This dissertation is a reflection not only of my efforts but also of the collective support, guidance, and belief of those around me—for which I am truly grateful.

Thank you Almighty!!

-Abna Sreedhar Vysiapat

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LIST OF ABBREVIATIONS

AI – Artificial Intelligence

API – Application Programming Interface

CAGR – Compound Annual Growth Rate

CCA – Country Coordinator Agreement

CDSCO – Central Drugs Standard Control Organization

CKD – Chronic Kidney Disease

COPD – Chronic Obstructive Pulmonary Disease

CRA – Clinical Research Associate

CRF – Case Report Form

CRO – Contract Research Organization

CT – Clinical Trial

CTA – Clinical Trial Agreement

CTA – Clinical Trial Associate

CTM – Clinical Trial Manager

DCGI – Drugs Controller General of India

DHT – Digital Health Technology

DT – Digital Twin

EMA – European Medicines Agency

EC – Ethics Committee

FDA – Food and Drug Administration (U.S.)

GCP – Good Clinical Practice

GDPR – General Data Protection Regulation

HPV – Human Papillomavirus

ICH – International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ICMR – Indian Council of Medical Research

IoT – Internet of Things

IRB – Institutional Review Board

ML – Machine Learning

NDHM – National Digital Health Mission

PI – Principal Investigator

PRECIOUS trial – Prevention of Complications to Improve Outcomes in elderly patients with Stroke

RCT – Randomised Controlled Trial

SME – Subject Matter Expert

TB – Tuberculosis

VHP– Voluntary Harmonisation Procedure

WHO – World Health Organization

XR – Extended Reality

ABSTRACT

Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India

Abna Sreedhar Vysiapat

Introduction

Clinical trials in India are often delayed due to regulatory bottlenecks, site-level inefficiencies, and patient recruitment challenges. Digital twin technology—virtual replicas of real-world processes—offers potential to streamline trials through simulation, optimisation, and predictive modelling. However, research on its application in India remains scarce. This study aimed to explore whether digital twins could help reduce trial delays and to assess the perceptions and readiness of clinical research professionals in India.

Methods

A mixed methods strategy was adopted, combining primary and secondary research. Surveys were conducted with 149 clinical research professionals to gather quantitative insights, while in-depth interviews with 8 experts provided qualitative perspectives. Quantitative data were analysed using descriptive statistics, and qualitative data were examined through thematic analysis to identify themes and sub-themes aligned with the research objectives.

Results

Findings showed that delays were primarily driven by slow regulatory approvals, ethics committee backlogs, site-level inefficiencies, and recruitment difficulties. Awareness of digital twins was limited, but professionals recognised their potential to improve protocol design, patient recruitment, and trial predictability. Key barriers included high costs, infrastructure limitations, regulatory uncertainty, and lack of expertise. Despite these obstacles, respondents expressed cautious optimism about adoption, citing ongoing digitalisation trends, workforce training, and evolving regulatory frameworks as enablers.

Conclusion

The study concludes that while India's clinical trials continue to face systemic delays, digital twin technology represents a promising avenue for improvement. The research fills a regional gap in the literature, offering both conceptual insights and practical recommendations for future adoption. Broader stakeholder engagement and pilot projects will be crucial to validate its effectiveness in real-world settings.

Keywords

Digital twins, Clinical trial delays, India, Mixed methods, pharmaceutical research, Regulatory challenges, Patient recruitment

Chapter 1
Introduction

INTRODUCTION

1.1 Overview

The pharmaceutical industry is under constant pressure to develop new drugs quickly and safely. However, one of the biggest challenges faced by pharmaceutical companies is the delay in clinical trials. These delays can happen due to slow patient recruitment, complex trial protocols, lack of real-time data, and regulatory issues. As a result, new treatments take longer to reach the market, affecting both business performance and patient care.

In recent years, digital twin technology has gained attention as a possible solution. A digital twin is a virtual model that mirrors real-world systems, allowing simulations, predictions, and better decision-making. In clinical trials, digital twins can be used to simulate trial outcomes, monitor patient data in real-time, and improve trial designs. This can reduce time, cost, and human error in the drug development process. (Sun *et al.*, 2023; Fischer *et al.*, 2024)

India is a fast-growing hub for clinical research due to its large patient population and skilled workforce. However, trial delays remain a major issue. This research aims to explore how digital twin technology could help reduce those delays in the Indian clinical trial system. It will gather views from professionals in the field and examine how prepared the country is to adopt this innovation.

1.2 Problem Statement

Clinical trials in India often face significant delays due to complex regulatory requirements, inefficient trial design, slow patient recruitment, and limited use of digital technologies. These delays can increase research costs, slow down the development of new medicines, and affect patient access to innovative treatments. While digital twin technology has shown promise in improving efficiency and accuracy in other sectors, its use in clinical trials—particularly in India—remains underexplored. There is a lack of awareness, limited infrastructure, and uncertainty about the practical application of digital twins in this field. This gap creates a need to investigate whether digital twins can be a viable solution to reduce delays in clinical trials in India, and how industry professionals perceive their potential use and challenges. The study aims to address this gap by gathering real-world insights from professionals working in clinical research and identifying ways digital twins could improve trial outcomes and processes.

1.3 Research Aim

The aim of this research is to explore how digital twin technology can be used to reduce delays in clinical trials in India by understanding its potential benefits, challenges, and practical applications from the perspective of clinical research professionals.

1.4 Research Objectives

- To identify and categorize the primary causes of clinical trial delays in India through a literature review
- To analyze the current adoption status of digital twin technology in the clinical research sectors of India
- To evaluate the potential of digital twins to mitigate specific delay factors (e.g., patient recruitment, trial protocol adjustments, regulatory approvals)

- To propose a strategic implementation framework that outlines 3–5 practical recommendations for leveraging digital twins to reduce trial delays in India

1.5 Research Questions

Below are the well-structured research questions:

1. What are the common causes of delays in clinical trials in India?
2. What is the level of awareness and understanding of digital twin technology among clinical research professionals in India?
3. How can digital twin technology potentially address the challenges faced during clinical trials in India?
4. What are the perceived benefits and limitations of using digital twins in the clinical trial process?
5. What factors could influence the adoption of digital twin technology in the Indian clinical research environment?

1.6 Research Hypotheses

Main Hypothesis:

Digital twin technology can significantly reduce delays in clinical trials in India by improving planning, monitoring, and decision-making processes.

Supporting Hypotheses:

- H1: Clinical research professionals in India have limited awareness and understanding of digital twin technology.
- H2: The adoption of digital twin technology in clinical trials is perceived to improve trial efficiency and reduce time to completion.
- H3: Key challenges to adopting digital twins in clinical trials include lack of infrastructure, training, and regulatory clarity.
- H4: There is a positive attitude among professionals towards integrating digital innovations like digital twins in future clinical trial strategies.

1.7 Link with the Program module

This research topic, "Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India," is closely linked to the Clinical Research Management module of the MSc in Pharmaceutical Business and Technology. The study directly addresses core themes of this module, such as clinical trial planning, execution, regulatory challenges, and innovations in research methods. By focusing on how digital twin technology—a cutting-edge digital

innovation—can improve clinical trial efficiency, the research highlights modern approaches to solving operational delays, a key concern in trial management.

Through primary data collection (interviews and surveys), the research applies theoretical knowledge from the module to practical industry scenarios, ultimately aiming to contribute meaningful insights that can support better trial management strategies in India and potentially other emerging markets.

1.8 Research Significance

This research explores the potential of digital twin technology to address delays in clinical trials in India, a country with a growing pharmaceutical market but ongoing challenges in research efficiency. The significance of this study lies in its ability to contribute to both academic understanding and real-world applications in the clinical research field. Clinical trial delays are a major concern globally, especially in developing economies where infrastructure, regulatory processes, and patient recruitment often pose barriers. By investigating how digital twins — virtual models that simulate real-world patients or trial processes — can support trial planning, monitoring, and outcome prediction, this research aims to provide practical insights into how innovation can improve timelines, reduce costs, and enhance decision-making in trials.

India is a key market for clinical research, and improving its trial efficiency can lead to faster access to life-saving drugs, improved global competitiveness, and better patient outcomes. While digital twin technology has shown success in areas like manufacturing and personalized medicine, its use in clinical trials is still emerging and underexplored, especially in the Indian context. This makes the topic highly relevant and timely. The study will gather opinions and insights from professionals such as clinical research associates, trial managers, and directors to understand how this technology is perceived and what challenges might arise in its adoption.

The findings could potentially guide pharmaceutical companies, policymakers, and clinical research organizations in adopting or planning for future use of digital twin technologies. It also opens doors for further academic studies in this field. Overall, the research aims to offer meaningful recommendations that could influence the way clinical trials are managed in India, aligning with global trends toward digital health innovation.

1.9 Access of Data and Ethics

For this research, data will be collected through online interviews and surveys involving professionals working in the clinical research and pharmaceutical sectors, such as Clinical Research Associates (CRAs), Clinical Trial Managers (CTMs), and/or Directors. Access to these participants will be gained through professional networks, referrals, and platforms like LinkedIn, using respectful and professional communication. All participants will be provided with a clear information leaflet and consent form outlining the purpose of the study, what participation involves, and their rights.

Ethical considerations will be strictly followed throughout the study. Participation will be entirely voluntary, and participants can refuse to answer any question or withdraw from the study at any time without facing any consequences. Anonymity and confidentiality will be

maintained by ensuring that no personal identifiers are linked to the data. All collected data, including audio recordings (if interviews are recorded), will be securely stored in a password-protected folder on a personal computer and will only be accessible to the researcher. The data will be retained in line with GDPR guidelines and institutional policy and deleted after the required retention period. If any risk of harm or serious issues arise during the research, appropriate steps will be taken, including the possibility of breaking confidentiality in line with ethical standards.

1.10 Structure of the research

This research is structured into five main chapters, each designed to build a clear understanding of the study's aim, background, methods, findings, and conclusions

- **Introduction**

This section introduces the research topic, outlines the problem of clinical trial delays in India, and explains the aim of exploring digital twin technology as a solution. It also includes the research objectives, questions, and significance of the study.

- **Literature Review**

This part reviews existing studies and theories related to clinical trials, digital twin technology, and their intersection. It identifies key debates, highlights gaps in the research, and sets the foundation for your study.

- **Research Methodology**

This section explains how the research was carried out. It describes the research philosophy (pragmatism), approach, data collection methods (interviews and surveys), participant selection, and ethical considerations.

- **Findings and Analysis**

Here, the collected data is presented and analyzed. Key patterns, themes, and insights from interviews and survey responses are discussed in relation to the research questions.

- **Conclusions and Recommendations**

This section summarizes the key findings, discusses their implications, and gives practical recommendations for improving clinical trial processes using digital twins. It also suggests areas for future research.

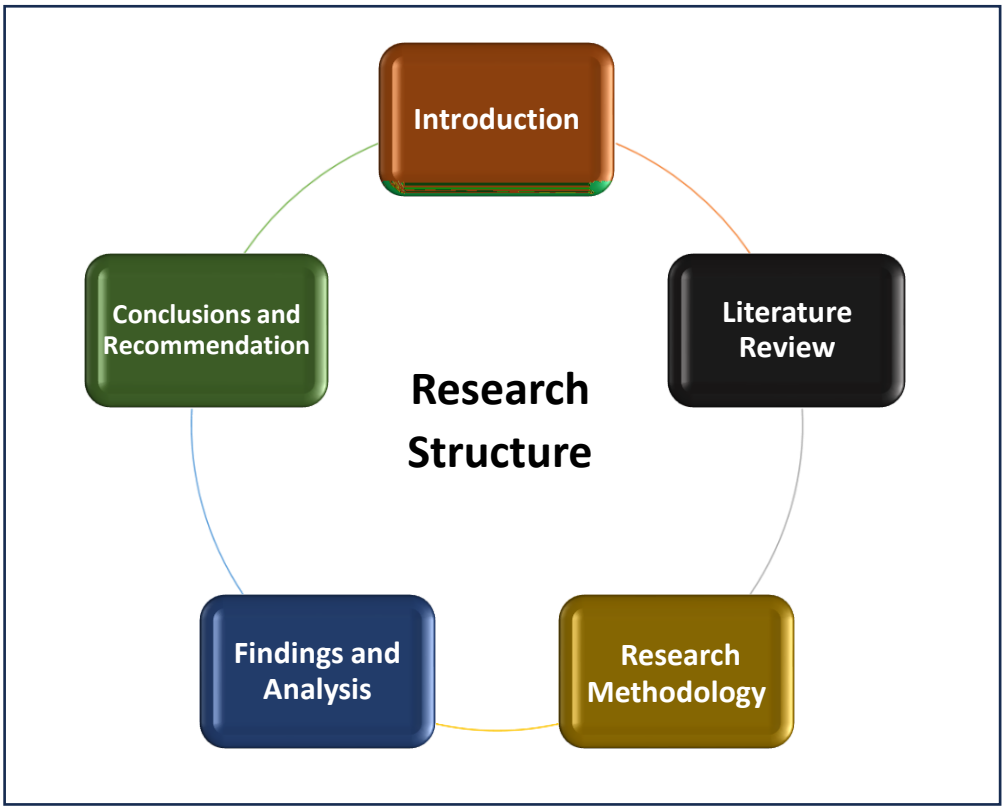

Fig. 1 Structure of Research (source: developed by Author)

Chapter 2
Literature Review

LITERATURE REVIEW

2.1 Introduction to the Literature Review

2.1.1 Purpose and importance of the literature review

The purpose of the literature review is to explore and understand what has already been studied and published about clinical trial delays and the use of digital twin technology. It helps to build a strong foundation for the research by identifying existing knowledge, key concepts, trends, and gaps in the field. This is important because it ensures that the research is relevant, focused, and adds value to the existing body of knowledge. By reviewing current studies, the literature review also helps to clarify the research problem, justify the research aim, and shape the methodology. It allows the researcher to critically analyse what has worked, what challenges exist, and what areas need further investigation—especially in relation to how digital twin technology might improve planning, monitoring, and decision-making in clinical trials. Overall, the literature review is a vital step that strengthens the research by making it more informed and evidence-based.

2.1.2 Scope of the Literature Review: Clinical Trials, Digital Twin Technology, and the Indian Context

The scope of this literature review focuses on three key areas: clinical trials, digital twin technology, and the Indian clinical research environment. It begins by examining the global clinical trial process, with special attention to common challenges such as delays in recruitment, regulatory approvals, and data management. The review then explores the concept of digital twin technology—its origin in engineering, its growing applications in healthcare, and its emerging role in improving the efficiency of research and development processes. The final focus is on the Indian context, highlighting the current state of clinical trials in India, challenges specific to the region, such as infrastructure, regulations, and resource availability, and how digital innovation could help address these issues. Together, these three areas help frame the research question and guide the study toward assessing the potential of digital twins to improve the speed and effectiveness of clinical trials in India.

2.1.3 Brief Overview of How Themes Will Be Structured

The literature review will be analysed using a thematic structure to clearly present key ideas and debates relevant to the research. It will begin with an overview of clinical trials, focusing on their phases, processes, and common causes of delays. The second theme will explore digital twin technology, including its definition, history, applications in healthcare, and potential role in clinical research. The third theme will link the first two by examining how digital twins can address specific challenges in clinical trials, such as planning, patient recruitment, monitoring, and data analysis. Finally, the review will cover the Indian context, outlining the current landscape of clinical trials in India, regulatory and operational barriers, and the readiness of the industry to adopt digital innovations. Throughout the review, gaps in the existing literature will be identified to highlight opportunities for further research.

2.2 Overview of Clinical Trials and Their Challenges

2.2.1 Definition and phases of clinical trials

A clinical trial is a carefully structured process used to check whether a new drug or medical device is safe and works well for treating, preventing, or diagnosing a health condition. These trials go through different stages, starting from early tests (called Phase 0 or micro-dosing studies), and moving through Phase 1 to Phase 4, described in Fig. 1, as the research progresses and more people get involved. (Kandi and Vadakedath, 2023; WHO, n.d.)

There are two main types of clinical research: observational (where researchers simply observe what happens without changing anything) and interventional (where researchers actively test a new treatment or approach).

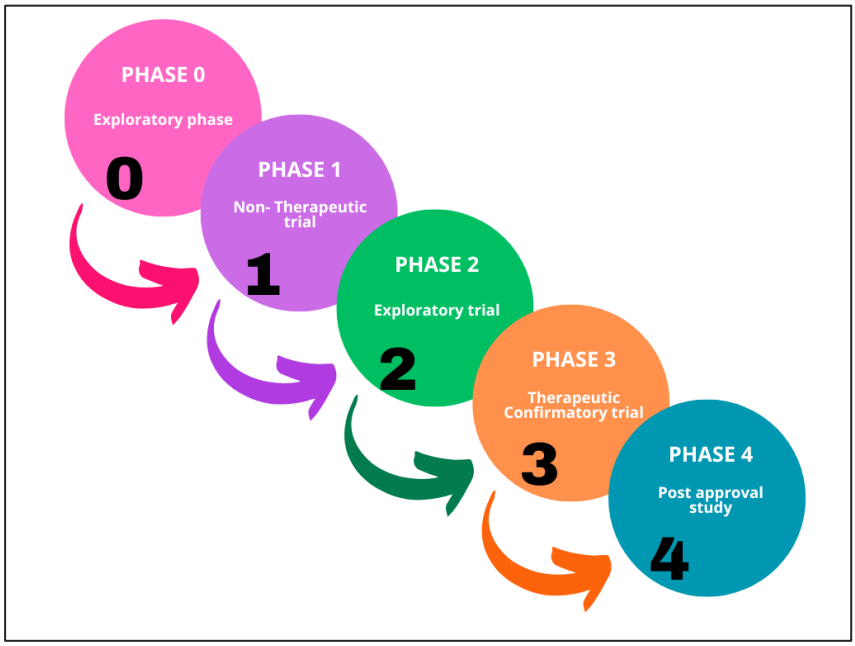

Fig. 2 Phases of clinical trials (Kandi and Vadakedath, 2023)

Clinical trials can be designed in different ways, depending on the goal of the study. Some common designs include parallel studies (where groups get different treatments at the same time), crossover studies (where participants switch treatments partway through), and factorial designs (which test more than one treatment at once). Other designs include randomized withdrawal, adaptive studies that can change along the way, and those that test whether a treatment is better (superiority) or just as good (non-inferiority) as another. (Kandi and Vadakedath, 2023)

Experimental study designs are generally divided into two types: controlled and uncontrolled. In an uncontrolled study, there's only one group that receives the treatment, and any outcomes are assumed to be caused by that treatment. However, this makes it hard to tell whether the results are truly due to the intervention or just happened by chance. To avoid this uncertainty, a controlled study design is used. This involves two groups—one that receives the treatment (the intervention group) and one that does not (the control group). Comparing these groups helps researchers draw more reliable and accurate conclusions about whether the treatment really works. (Chidambaram and Josephson, 2019)

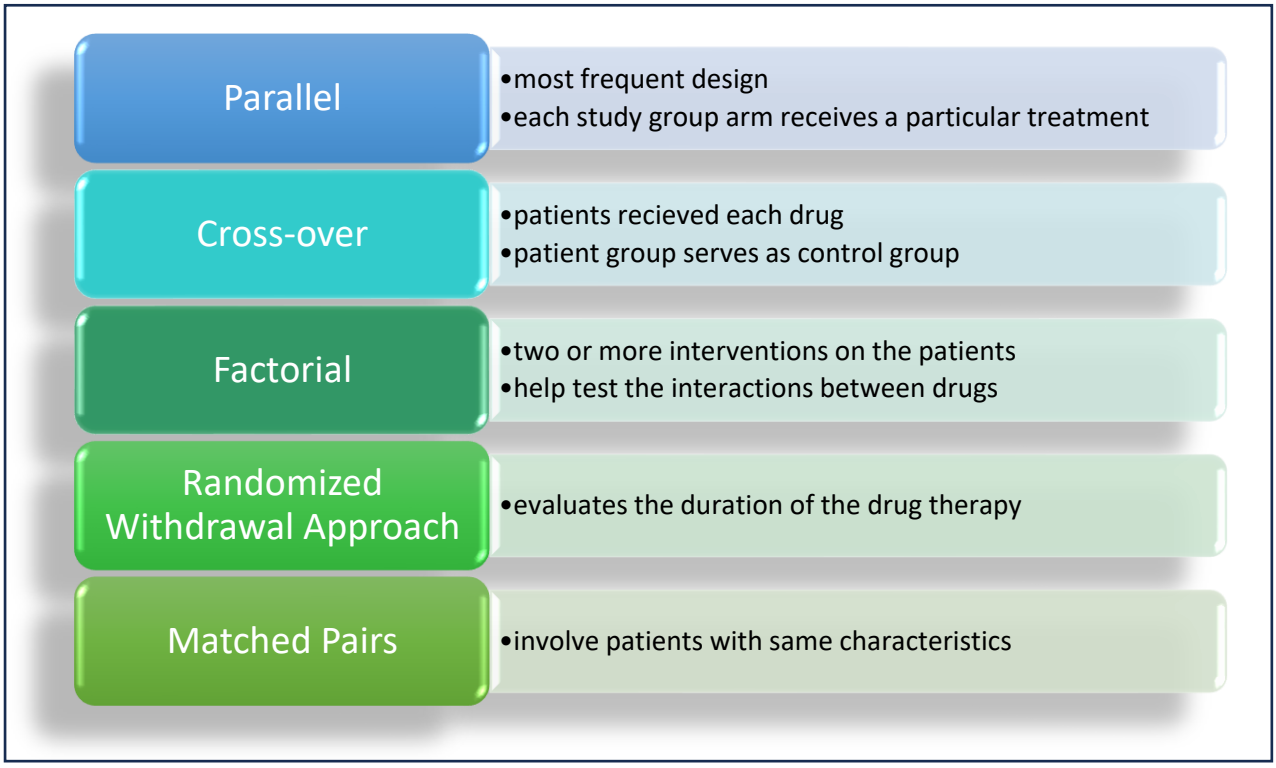

Fig. 3 Types of study designs in Clinical trials (Chidambaram and Josephson, 2019; Kandi and Vadakedath, 2023)

Randomization plays a crucial role in reducing bias and ensuring the reliability of clinical trial results. Several methods are commonly used, depending on the study design and objectives. Simple randomization involves assigning participants to either the treatment or control group using methods like a coin flip or computer-generated sequences. (Kandi and Vadakedath, 2023)

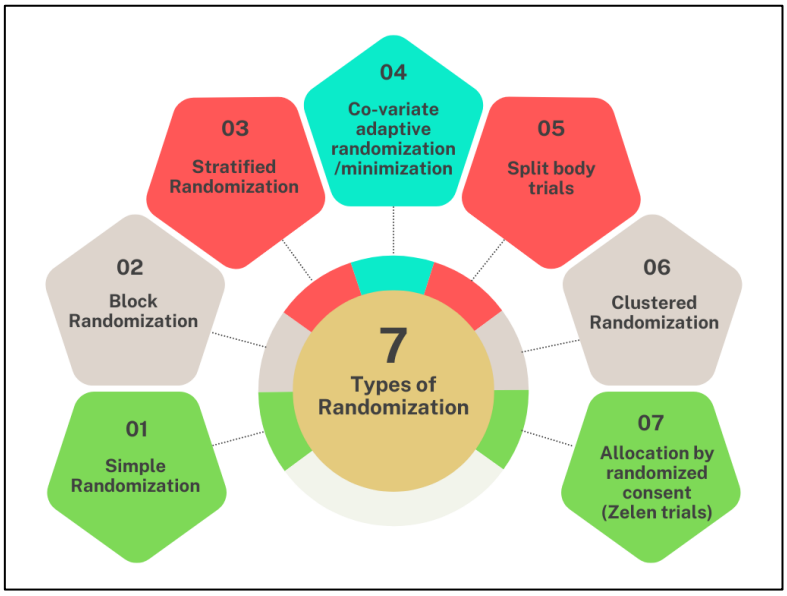

Fig. 4 Types of Randomizations involved in study designs (Chidambaram and Josephson, 2019; Kandi and Vadakedath, 2023)

Block randomization ensures that participants are evenly distributed into small, balanced groups across both arms of the trial. Stratified randomization goes a step further by grouping participants based on key characteristics, such as age or other relevant variables, to ensure these factors are equally represented (Chidambaram and Josephson, 2019). Covariate adaptive randomization, also known as minimization, involves assigning each new participant to a group based on the characteristics of those already enrolled, helping maintain balance across important variables. In split-body trials, often used in dermatology or ophthalmology, one treatment is applied to one side of the body or one organ, while the comparison treatment is applied to the other, allowing for within-subject comparisons. Cluster randomization assigns entire groups or clusters—such as clinics, schools, or communities—to different treatments to prevent cross-contamination between groups. Lastly, randomized consent or Zelen trials involve assigning patients to trial arms before obtaining consent, a method designed to reduce selection bias and improve trial participation (Chidambaram and Josephson, 2019; Kandi and Vadakedath, 2023).

2.2.2 Importance of clinical trials

According to Haofuzi Zhang and Xiaofan Jiang (Zhang and Jiang, 2025), clinical trials are a cornerstone of Evidence-Based Medicine, working in tandem with systematic reviews and meta-analyses to ensure reliable and well-informed medical decisions. The strength of meta-analyses often depends on the volume and quality of clinical trials included, making these trials vital for confirming the true effectiveness of new medical interventions. Clinical trials not only help determine whether a treatment is safe and effective but also form the scientific foundation for therapeutic approvals and clinical guidelines. By carefully evaluating outcomes through well-structured trials, researchers are able to contribute to a broader understanding of medical practices grounded in strong empirical evidence.

Zhang and Jiang further emphasize that clinical trials carry a wide range of public health benefits. They highlight how trials lead to new treatments for conditions that may have had limited or no options in the past, ultimately improving patient outcomes and quality of life (Zhang and Jiang, 2025). Moreover, by comparing newer therapies to existing ones, clinical trials can reveal cost-effective solutions with fewer side effects, helping to manage rising healthcare costs. The authors also note the value of clinical trials in deepening scientific knowledge about disease biology and mechanisms of drug action. This insight can inspire the development of novel therapies. Importantly, they stress the essential role of clinical trials in addressing rare diseases, where patient populations are small and research is often limited—underscoring the need for continued innovation and tailored trial designs to support these underserved communities (Kshirsagar *et al.*, 2023; Zhang and Jiang, 2025)

2.2.3 Key stakeholders in clinical trials

Clinical trials (CTs) are generally carried out within healthcare settings, where researchers are often practicing clinicians. In this context, the healthcare system serves a dual purpose: not only providing care to improve patients' health but also contributing to the development of new therapies, frequently in collaboration with the pharmaceutical industry. Balancing these two missions—clinical care and research—requires a well-structured support system and a strong organizational framework. To ensure quality and ethical standards, clinical trials follow the Good Clinical Practice (GCP) guidelines, as outlined by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), which

serve as the global benchmark for conducting reliable and ethical trials (Peralta and Sánchez-Santiago, 2024).

The roles that form the foundation of clinical trial operations are mentioned as follows:

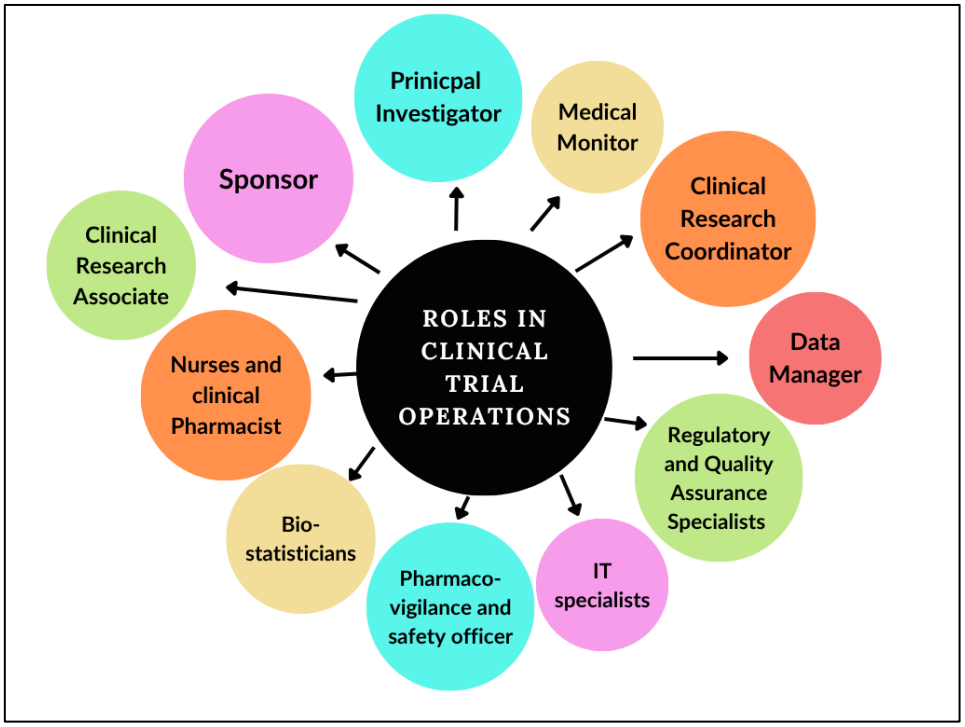

Fig. 5 Main roles involved in clinical trials operations (Peralta and Sánchez-Santiago, 2024; International Council for Harmonisation, 2025)

2.2.4 Challenges in Clinical Trails

Clinical trials are a critical step in the development of new drugs and therapies, but they are often hindered by significant challenges that impact both timelines and costs. Delays can occur at various stages of a trial, from patient recruitment and site initiation to data collection and regulatory approvals. These setbacks not only increase the financial burden on pharmaceutical companies but also slow down patient access to potentially life-saving treatments. Research shows that over 80% of clinical trials face delays, with patient recruitment being the leading cause. In countries like India, additional factors such as regulatory hurdles, infrastructure gaps, and limited technological adoption further contribute to extended timelines. Addressing these delays is essential for improving efficiency, reducing costs, and accelerating the overall drug development process, which is why innovative technologies like digital twins are being explored as potential solutions.

❖ Delays in Patient recruitment

Recruiting the right number and mix of participants is one of the most difficult steps in clinical research. In many studies, recruitment becomes the single biggest operational hurdle—often more challenging than designing the protocol or running the sites. How (and whom) we sample is shaped by multiple, very practical constraints: ethics, money, infrastructure, timelines, and a host of other contextual factors. Getting this wrong doesn't just slow a study down; it can

weaken the quality, validity, and regulatory acceptability of the results—particularly when the trial supports approval of a new medicine. (Kandi and Vadakedath, 2021)

Some areas of research are hit especially hard. Trials in rare genetic disorders or paediatric populations frequently struggle to find enough eligible participants. On the other end of the spectrum, the under-representation of older adults has been recognised for decades. Barriers here include frailty, multimorbidity, polypharmacy, different health beliefs, and health-system differences across countries**.** These make it harder to design a "one-size-fits-all" protocol or recruitment plan for large, international randomised controlled trials (RCTs). Investigators also report that recruiting older adults is time-consuming and labour-intensive, requiring tailored communication, extra visits, or caregiver involvement (Buttgereit *et al.*, 2021).

Recruitment is only half the battle—retention can be equally tough. Whether participants stay in a trial often depends on the disease area, symptom burden, visit frequency, travel demands, and how long the study runs. Long durations are repeatedly cited as a major driver of drop-outs, threatening statistical power and interpretability. Designing participant-centred protocols (shorter visits, remote monitoring, flexible scheduling) and clear communication throughout the study can help keep people engaged (Buttgereit *et al.*, 2021).

Estimating the additional costs of patient recruitment beyond standard remuneration is challenging and often varies significantly, even within the same therapeutic area. Recruitment and retention efforts are frequently hampered when patients express concerns about being placed in a control group instead of receiving the active treatment. This hesitation is often linked to a limited understanding of placebos or uncertainty about the treatments given in control arms (Fogel, 2018).

A recurring issue highlighted in the literature is that many study centres report fewer eligible patients than initially projected. In contrast, centres with a proven history of strong recruitment performance are typically more successful in meeting enrolment targets. Considering the substantial number of clinical trials that fail or experience major delays due to poor recruitment and retention, it becomes critical during trial design and execution to account for the burden placed on participants. Higher patient burden, whether due to frequent visits, travel requirements, or invasive procedures, is strongly associated with reduced retention. While all forms of burden must be addressed, the financial implications for participants warrant particular attention, as these can directly impact both willingness to participate and completion rates (Fogel, 2018).

❖ Regulatory Hurdles

Regulatory and ethical considerations are among the most significant challenges in the timely initiation of clinical trials. Delays in regulatory agency approvals are common due to complex documentation requirements, stringent reviews, and a lack of harmonized processes across different regions. Similarly, delays between ethics submission and approval often occur, as ethics committees may require multiple rounds of clarifications or revisions to ensure participant safety and adherence to ethical standards. Another notable challenge is the limited familiarity of ethics committee members with the Indian Council of Medical Research (ICMR) guidelines, particularly in the context of conducting clinical trials during a pandemic, which can further prolong the review process. Additionally, infrequently scheduled ethics committee meetings can lead to unnecessary waiting times, delaying crucial decisions and ultimately

slowing the overall start-up of clinical studies. Addressing these issues requires better training for ethics committees, more frequent review meetings, and harmonized regulatory frameworks to streamline the approval process (Bassi et al., 2022).

In their study on regulatory delays in the PRECIOUS multinational stroke trial, De Jonge *et al*. (De Jonge *et al.*, 2021) highlight the extensive time required to initiate clinical trial sites across Europe, reporting a median delay of 784 days (approximately 26 months) before patient recruitment could begin. The authors identify contract negotiations, particularly the Country Coordinator Agreement (CCA) and the Clinical Trial Agreement (CTA), as the main contributors to these delays, together accounting for nearly one-third of the start-up period. Additional delays were caused by multiple layers of approvals from ethics committees, national regulatory authorities, and the Voluntary Harmonisation Procedure (VHP), which often added complexity rather than accelerating the process. De Jonge and colleagues emphasize that these prolonged start-up times negatively impact patient recruitment, as sites with longer set-up phases showed slower enrolment during the initial six months. They suggest that improvements such as standardized contracts, streamlined national reviews, and stricter timelines are necessary to enhance the efficiency of academic clinical trials across multiple countries.

Jennifer Lai et al (Lai *et al.*, 2021) examine the critical factors that contribute to regulatory delays during the start-up phase of clinical trials. Their literature review identifies six key drivers of these delays: disparate regulations across countries, which create inconsistencies and increase the complexity of submissions; submission delays due to the extensive documentation required; and additional requirements that arise even after regulatory approval, leading to further setbacks. The authors also highlight the role of local ethics committees or institutional review boards (IRBs), whose limited familiarity with global regulatory standards and infrequent meeting schedules often result in prolonged approval times. Lastly, they point out regulatory backlogs and clock-stops, where review processes are paused for clarifications or additional information, as significant contributors to delays. Lai and colleagues emphasize the need for harmonized regulations, streamlined processes, and improved coordination among regulatory and ethics bodies to accelerate the start-up timelines of global clinical trials.

❖ Operational complexities

Site-level challenges are another major factor contributing to delays in clinical trial start-up and execution. Studies highlight that issues with site set-up and the delegation of responsibilities can slow trial initiation, particularly when there is a lack of clarity in roles and operational workflows. A limited prior experience with trial conduct and the use of digital platforms among some sites further complicates the process, requiring additional training and support. The restricted ability of trial management teams to conduct on-site visits, often due to travel limitations such as those seen during the COVID-19 pandemic, has also hindered oversight and delayed key activities like site activation. Moreover, ensuring source data verification and data integrity becomes challenging in such circumstances, especially when remote monitoring tools are not fully integrated. Finally, low participation from smaller or remote health units, which may lack the infrastructure or resources to meet trial requirements, further limits the pool of active trial sites and contributes to overall delays.

Site contracts and budgets are recognized as significant contributors to start-up delays in clinical trials, as highlighted in the literature. The negotiation of clinical trial agreements (CTAs) and investigator grants (site budgets) between sponsors and clinical sites is often time-

consuming, taking months to finalize and execute. An additional challenge is the procurement of liability insurance, which, despite being critical for trial initiation, is often underestimated by clinical trial managers. The supply chain for clinical materials also poses substantial hurdles, particularly in international trials, where preparing and delivering supplies to remote regions is complicated by varying language and regulatory requirements in each country (Lai *et al.*, 2021)

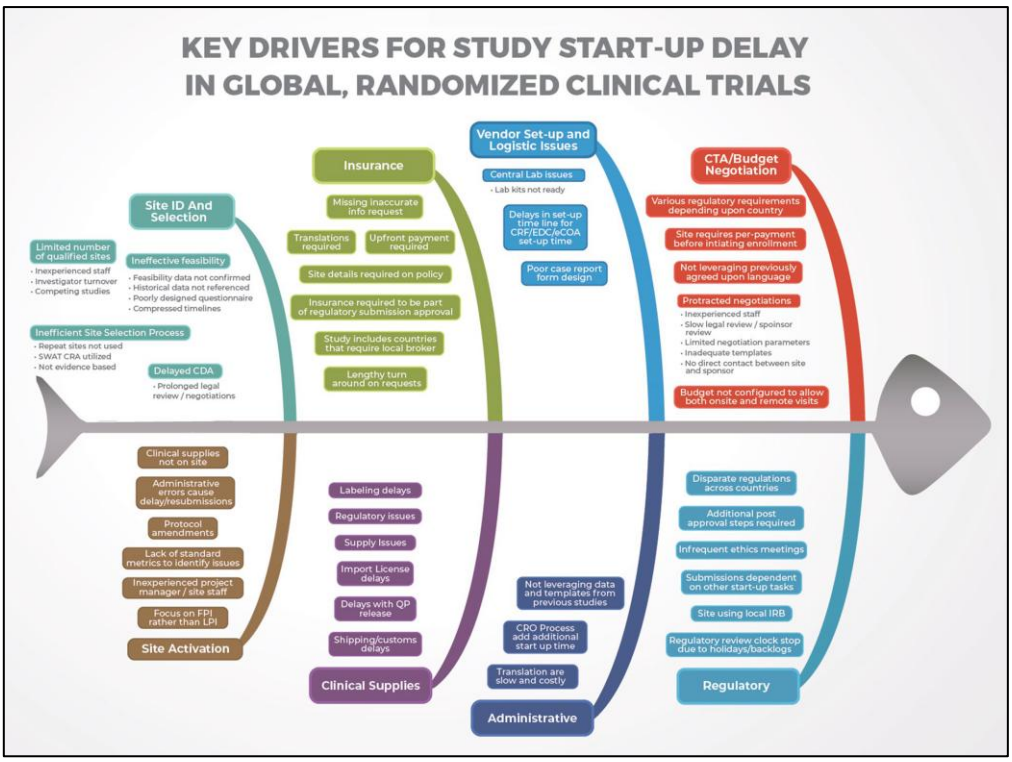

Fig. 6 Key Drivers for Study Start-up Delay in Global, Randomized Clinical Trials (Lai et al., 2021)

Moreover, the competition for qualified and experienced clinical sites has intensified, making site selection a significant challenge, particularly for complex studies. Sponsors and contract research organizations (CROs) face additional delays due to the extensive documentation required before a site can be activated, including IRB/EC approvals, signed contracts, finalized budgets, FDA Form 1572 (or its equivalent), investigator CVs, medical licenses, and financial disclosure forms for the principal investigator and sub-investigators. These administrative and logistical complexities often create bottlenecks, further extending the start-up phase of global clinical trials (Lai *et al.*, 2021).

❖ <u>Miscellaneous Delays Impacting Clinical Trials</u>

A significant challenge encountered in clinical research is the widespread dissemination of misinformation, particularly the premature endorsement of treatments lacking robust scientific evidence. Such premature recommendations can undermine the integrity of clinical investigations and complicate the recruitment and retention of trial participants. Additionally, there is a notable reluctance among some clinicians to engage in randomized controlled trials (RCTs). This hesitancy may stem from concerns about trial design, ethical considerations, or potential impacts on clinical practice, further hindering the advancement of evidence-based medicine (Bassi et al., 2022).

Clinical trials often face a range of logistical and technological challenges that can impact their execution and data integrity. Data management is frequently complicated by technological limitations such as inadequate internet bandwidth, restrictive institutional firewalls, and limited availability of appropriate devices, all of which can hinder timely and accurate data collection and entry (Gumber *et al.*, 2024).

In terms of intervention management, obtaining necessary import permits for trial materials poses significant difficulties, contributing to delays in study commencement and progression. Furthermore, drug wastage, shipment delays, and errors remain persistent problems that affect resource utilization and trial timelines. Adaptive protocol amendments, particularly in multi-arm studies, add complexity to drug supply logistics and data analysis processes, necessitating careful coordination to ensure trial validity and efficiency (Gumber *et al.*, 2024).

Clinical trial failures can result from various factors, including lack of efficacy, safety concerns, insufficient funding, and procedural shortcomings such as non-compliance with good manufacturing practices or regulatory guidelines. Additionally, difficulties in patient recruitment, enrolment, and retention further contribute to trial discontinuation (Fogel, 2018).

Among these, the primary cause of failure remains the inability to demonstrate therapeutic efficacy. In a study by Hwang *et al*, an analysis of 640 phase 3 trials involving novel therapeutics revealed a failure rate of 54% during clinical development, with 57% of these failures attributed specifically to inadequate efficacy. Safety issues also account for a notable proportion of trial failures; the same study identified safety concerns as the reason for failure in 17% of the phase 3 trials examined. While safety assessments are integral to all trial phases, adverse effects often become evident only in larger patient populations characteristic of phase 3 studies or emerge post-approval during phase 4 or post-market surveillance (Hwang et al., 2016).

In conclusion, while India holds significant potential as a global hub for clinical research due to its diverse patient population, skilled workforce, and cost advantages, persistent challenges such as regulatory delays, ethics committee inefficiencies, and site-level operational barriers have slowed progress in drug development. Addressing these issues requires a streamlined regulatory framework, faster and harmonized ethics reviews, and capacity-building initiatives to enhance digital readiness and site capabilities. Adopting global best practices—such as standardized contracts, risk-based monitoring, and centralized ethics approvals—can significantly reduce start-up times and improve trial efficiency. With these improvements, India can strengthen its position in the global clinical research landscape, accelerating the delivery of innovative and affordable therapies to patients while fostering a more robust ecosystem for pharmaceutical innovation.

2.3 Digital Twin Technology: Concept and Applications

2.3.1 Introduction to Digital Twin Technology

Digital technology has transformed multiple sectors, including education, industry, and research, and its impact on healthcare has become particularly significant in recent years. The concept of digital health is rapidly evolving and has gained unprecedented importance during the COVID-19 pandemic, where social distancing measures and lockdowns necessitated the widespread adoption of digital health solutions and technologies worldwide. As digital health continues to expand its role and influence in India, it becomes crucial to critically evaluate the current digital health infrastructure, identify the key challenges hindering its full potential, and explore strategies for its future development and integration into the healthcare system (Kapoor, 2022).

Digital transformation has emerged as a dominant trend in recent years, driven by the rapid development of advanced technologies aimed at enhancing efficiency and innovation across various sectors. Among these advancements, digital twin technology has gained significant attention as a key enabler of digital transformation. A digital twin involves creating a virtual replica of a physical object or system in the digital environment, enabling researchers and industries to simulate, monitor, and predict real-world scenarios. By providing insights into potential future outcomes, digital twins offer powerful tools for problem-solving, process optimization, and informed decision-making in complex real-world settings (Jeong *et al.*, 2022)

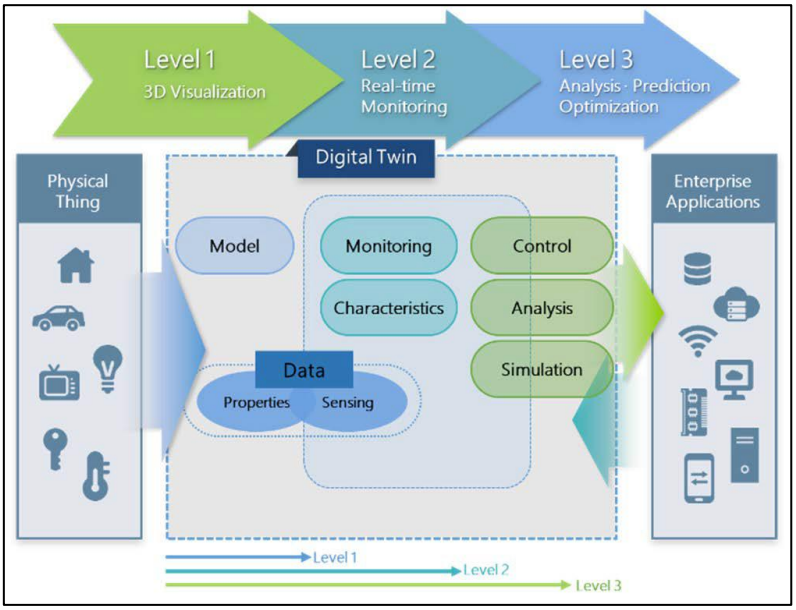

Fig. 7 Traditional digital twin evolution model. (Jeong et al., 2022)

According to Global Market Insights, the digital twin market, valued at approximately $8 billion in 2022, is projected to grow at a compound annual growth rate (CAGR) of around 25% between 2023 and 2032. Similarly, a recent global technology research report predicts that the market will expand by nearly $32 billion between 2021 and 2026. Furthermore, a 2022 survey revealed that nearly 60% of industry executives across various sectors plan to integrate digital twin technologies into their operations by 2028. These projections highlight the rapid adoption and growing importance of digital twins in shaping future industrial and technological landscapes (Attaran and Celik, 2023).

2.3.2 Types of Digital twin technologies

A Digital Twin relies on four core technologies to collect and store real-time data, generate meaningful insights, and create an accurate digital representation of a physical object. These foundational technologies include the Internet of Things (IoT), Artificial Intelligence (AI), and Cloud Computing. Depending on the specific application and its requirements, a digital twin may utilize these technologies to varying degrees, with certain components playing a more dominant role to optimize performance and outcomes (Armeni *et al.*, 2022; Attaran and Celik, 2023)

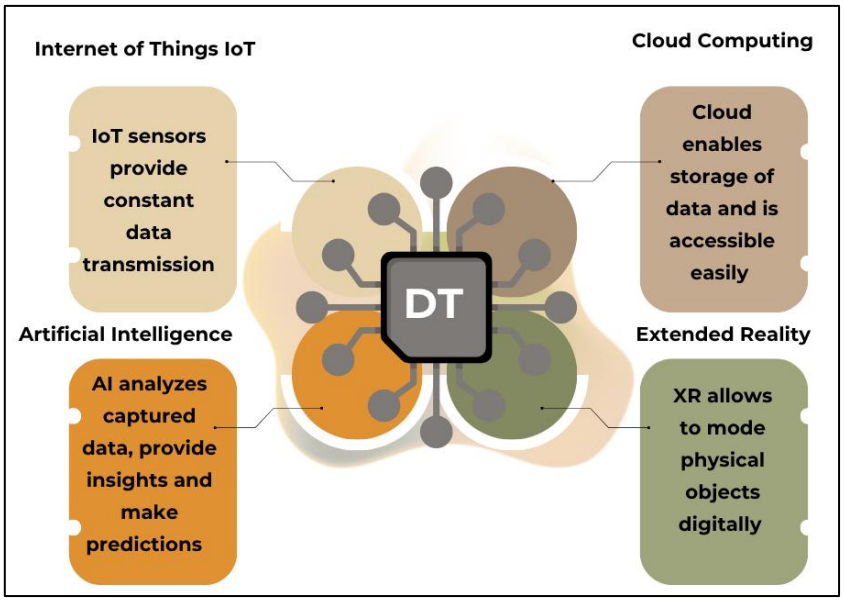

Fig. 8 Core technologies for Digital twins (Armeni et al., 2022; Attaran and Celik, 2023)

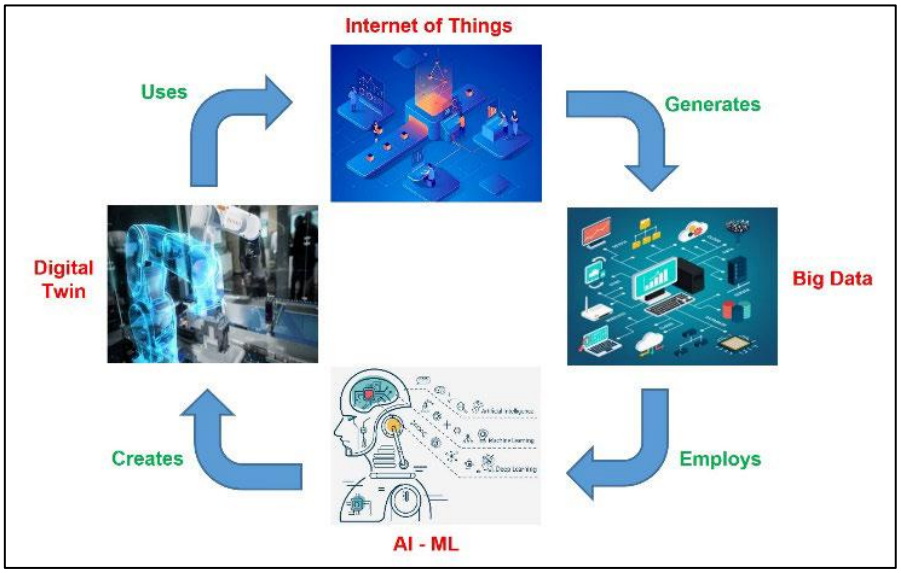

Fig. 9 DT relationship with IoT, Big Data, and AI-ML (Khan et al., 2022)

2.3.3. Layers of Digital twin Implementation

Layer 1 – Digital Virtualization: This layer of a Digital Twin leverages technologies like data preprocessing, multidimensional analysis, distributed storage, object visualization, and virtual sensors to collect, process, and optimize real-world data, enabling accurate digital representations and insights.

Layer 2 – Digital Twin Synchronization: This layer focuses on connecting and synchronizing real-world objects with their digital counterparts using technologies for efficient data transmission, verification, updating, and space-time synchronization, ensuring seamless communication and real-time interaction between physical and virtual systems.

Layer 3- Modelling and Simulation: This layer focuses on modelling digital twin objects and running simulations—using physics and behaviour modelling, system rules, and scenario generation—to solve real-world problems, with verification and certification ensuring accurate and reliable simulation outcomes.

Layer 4 - Federated Digital Twin: This implementation layer focuses on building large-scale digital twin systems by enabling collaboration and information exchange between multiple digital twin models through technologies like identification system management, federation metadata creation, and federation intelligence.

Layer 5- Intelligent Digital Twin Services: This layer focuses on a unified platform for managing digital twin services, including high-speed visualization, intelligent resource management, service evaluation, fault detection, and predictive maintenance, enabling efficient and intelligent service operations.

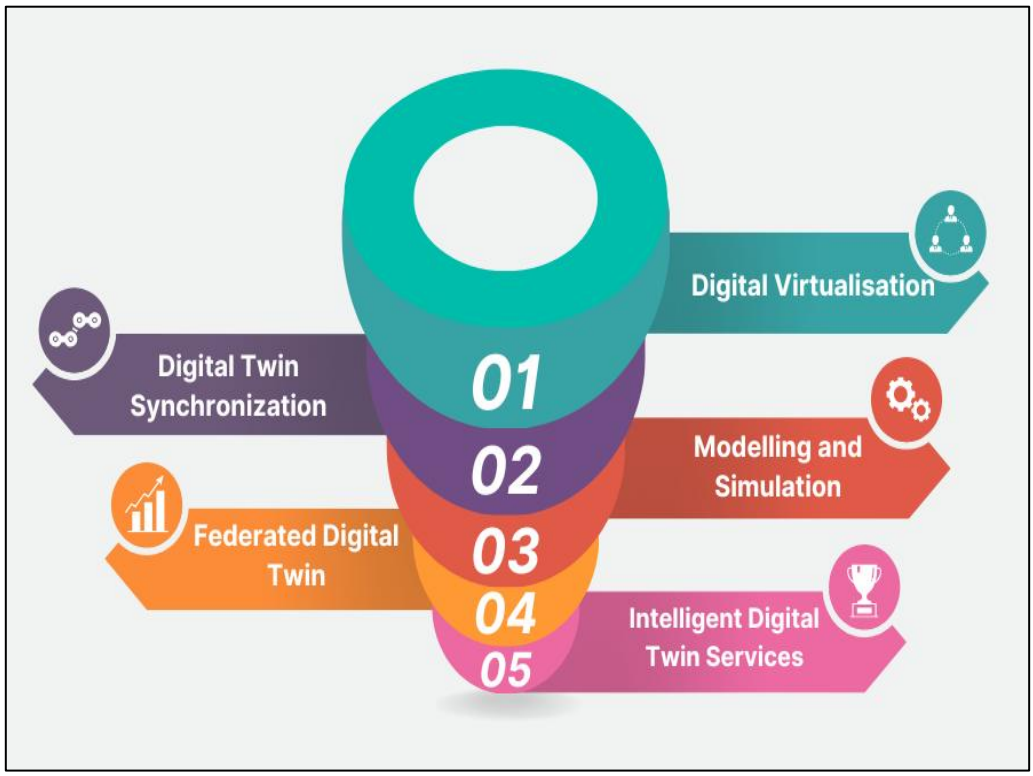

Fig. 10 Digital twins Implementation layers (Jeong et al., 2022)

2.3.4 Application of Digital Twins

Today, Digital Twins are widely used in engineering and manufacturing to create accurate virtual models of physical objects and simulate how they operate in real-world scenarios. Their potential is also being explored across operations and supply chain management, particularly in areas like traceability, transport maintenance, remote support, asset visualization, and personalized design. As this technology evolves, its impact is expanding beyond traditional industries into sectors such as automotive, aerospace, construction, agriculture, mining, utilities, retail, healthcare, defense, natural resources, and public safety. The growing interest from researchers, industry professionals, and decision-makers reflects the vast possibilities Digital Twins offer, and new applications are continually being introduced and discussed in academic and professional circles (Attaran and Celik, 2023)

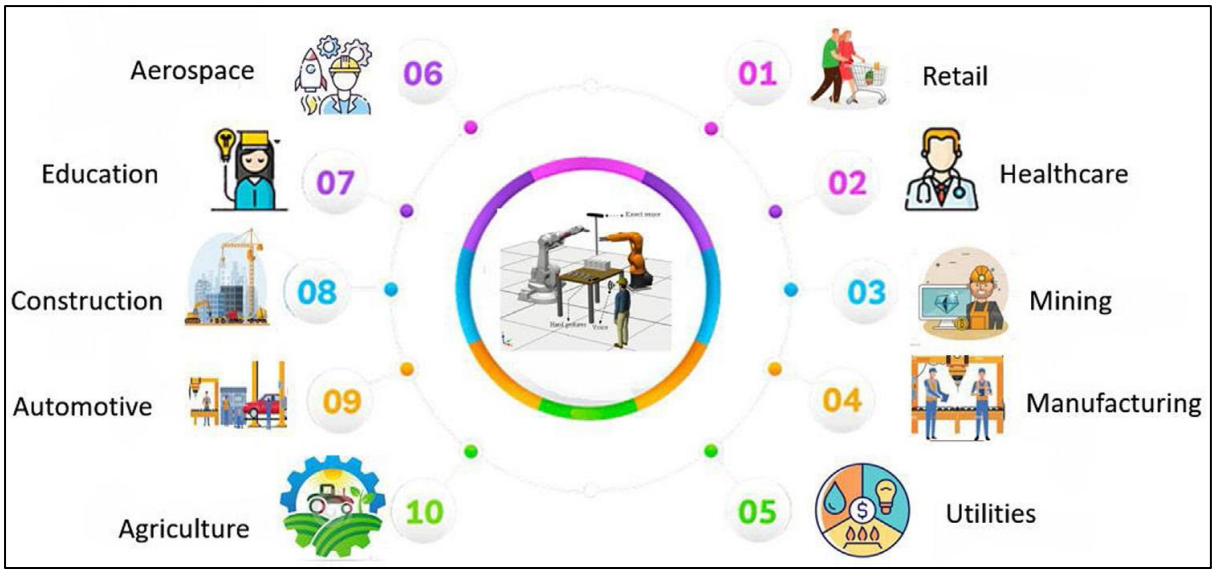

Fig. 11 Industries using Digital Twins (Attaran and Celik, 2023)

Overview of how Digital Twin technology is being used across different industries. Summary for each sector mentioned below:

1. Manufacturing

- Helps in customizing designs, simulating development steps, improving operations, cutting engineering costs, and performing predictive maintenance.

2. Aerospace/Automotive

- Used for customizing designs, detecting defects, tracking aircraft, predicting weather, optimizing transport, and real-time monitoring.

3. Construction/Real Estate

- Supports automated project control, safety, logistics, space evaluation, and building quality and performance assessments.

4. Utilities

- Improves planning and efficiency of power grids, offers better grid visibility, self-evaluation, and supports eco-friendly upgrades.

5. Agriculture/Farming

- Enables smart farming, helps plan and monitor farm activities, predicts weather, identifies stress in crops, and monitors livestock.

6. Healthcare

- Aids in diagnosis, therapy, preventive care, drug and device development, facility design, and staff training.

7. Retail

- Enhances supply chain management, product development, route planning, and store or facility design.

8. Mining

- Boosts machine efficiency, provides realistic training, supports drug/device development, and helps with design and training needs.

Overall, Digital Twins are being applied in many ways to improve efficiency, safety, and innovation across various industries.

2.3.5 Digital twins in Healthcare

The combination of Digital Twin technology, IoT data, and big data analytics is driving major advancements in healthcare. From reducing costs to improving diagnosis, therapy, and preventive care, these technologies are transforming how the sector operates. They enhance the use of medical devices, support drug development and clinical research, and enable more personalized healthcare experiences. Additionally, they help optimize hospital layouts and improve medical education and training. The push for digital transformation in healthcare has only accelerated since the COVID-19 pandemic, highlighting the urgent need for smarter, more connected solutions (Khan *et al.*, 2022; shilpa shinde, 2024)

In their article, Alexandre Vallée (Vallée, 2023) highlights how Digital Twin technology is reshaping the patient experience by encouraging more active involvement in personal healthcare. By giving individuals access to their own digital twin data—such as tailored health insights, treatment plans, and progress updates—patients are empowered to take greater control of their health journey. This empowerment not only improves adherence to prescribed treatments and lifestyle changes but also fosters stronger habits around self-care. Vallée also emphasizes the role of digital twins in enhancing communication between patients and healthcare professionals, supporting shared decision-making and advancing more personalized, patient-centered care.

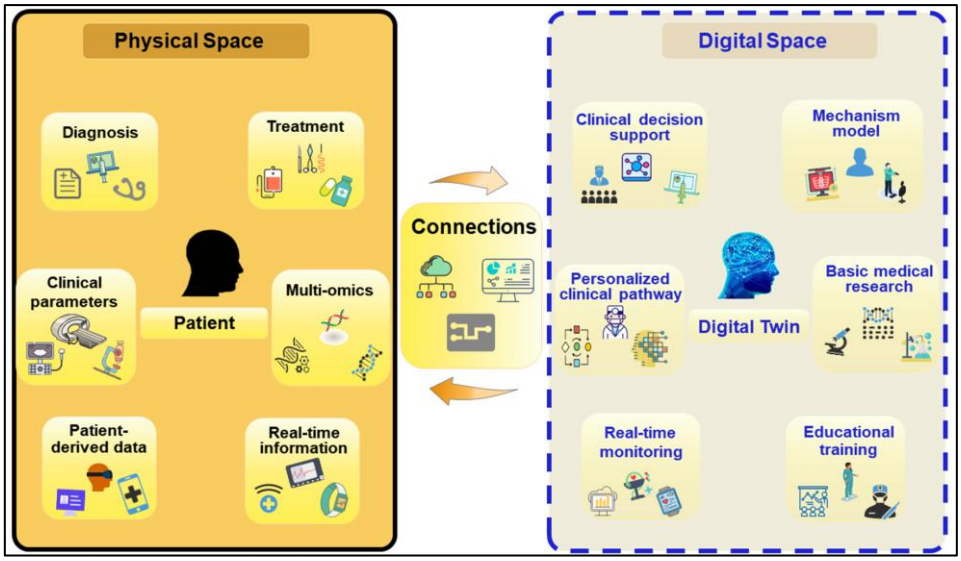

Fig. 12 Application and prospects of digital twin technology in the medical field. (Sun et al., 2023)

2.3.6 Digital twins in Clinical Trials

Beyond their growing role in diagnosis and treatment, Digital Twins (DTs) are showing promising potential in improving the development of new therapies—particularly in clinical trials. One of the major hurdles in clinical research is participant enrolment, with around 80% of trials facing delays at this stage and 20% failing to meet recruitment targets altogether. Challenges like identifying suitable candidates and the shift toward personalized medicine—where target populations are smaller—are making trials increasingly costly and inefficient. DTs could offer a breakthrough by creating virtual replicas of real patients that can be used to simulate different drug treatments, acting as computational control groups. This approach could speed up early-stage research, reduce the risk to actual patients, and significantly cut down the number of physical trials needed. While their current use in clinical trial support is still limited, early studies suggest that DTs have the potential to design smaller, more statistically powerful studies and even help salvage ongoing trials suffering from low enrolment or high dropout rates. In the near future, they are expected to enhance the reliability and efficiency of randomized controlled trials without compromising scientific integrity (Armeni *et al.*, 2022)

In his article, Douglas L. Mann, MD, explores how Digital Health Technologies (DHTs), including Digital Twins, can enhance the clinical trial process, particularly in Phase I and II studies. Phase I trials, traditionally conducted with small groups of healthy volunteers, focus on identifying safe dosage levels and potential side effects. However, these early trials may not accurately reflect how patients with the targeted disease will respond due to differences in health conditions and concurrent treatments. Mann highlights how DHTs can complement these studies by simulating patient-specific responses, helping to predict safety concerns and optimize dosing before moving to real-world testing. As trials progress to Phase II—where effectiveness is assessed in a larger group of patients—DHTs offer even greater value. With around 80% of trials facing delays due to slow enrolment, digital technologies can reduce the number of participants required, speeding up development while lowering costs and minimizing patient burden. This is particularly impactful for rare or orphan diseases, where finding eligible trial participants is especially challenging (Mann, 2024).

2.3.7 Challenges in Digital Twin technology implantation

While Digital Twin (DT) technology holds great promise, several significant challenges may slow its adoption, especially in healthcare. One of the biggest hurdles is the high cost of deployment. Building and maintaining Digital Twins requires substantial investment in advanced technologies—such as sensors, software platforms, and data infrastructure—as well as ongoing maintenance, power, and storage. Integrating DTs with existing legacy systems or proprietary software can also be complex and resource-intensive. The overall architecture of Digital Twins is intricate, and for many organizations, especially in resource-limited settings, these upfront and operational costs can be a major barrier to implementation (Attaran and Celik, 2023)

Beyond technical and financial concerns, ethical and policy-related issues also pose serious challenges. For Digital Twins to function effectively in healthcare, they need continuous access to sensitive patient data, including physical, biological, and lifestyle information. This raises critical concerns about privacy, security, and data ownership. There is also the risk of bias—many existing healthcare datasets disproportionately represent certain groups (like white males), leading to skewed results and potentially unequal treatment outcomes. Additionally, the insights DTs offer into genetic traits may lead to uncomfortable ethical questions, such as what constitutes a "favorable" genetic profile. Finally, as a relatively new technology in the healthcare space, there is still no clear business model to ensure equitable access, which risks leaving out vulnerable or underrepresented populations from its benefits. These concerns highlight the need for thoughtful regulation, ethical oversight, and inclusive design as the technology continues to evolve (Armeni *et al.*, 2022; Attaran and Celik, 2023)

A key social barrier to the adoption of Digital Twin (DT) technology in healthcare is the mistrust many clinicians have toward decisions made by algorithms and big data systems. Physicians often hesitate to rely on these tools because the reasoning behind their recommendations isn't always transparent or easy to understand. This lack of clarity can be especially concerning in high-stakes environments where a misdiagnosis or inappropriate treatment could have serious consequences. Additionally, there is a growing fear among healthcare professionals that DTs might eventually replace human clinicians in certain roles, particularly as these technologies become more capable of analyzing vast amounts of patient data quickly—something that's difficult to achieve in the time-limited setting of a typical medical consultation. These concerns highlight the need for DT systems to be designed with transparency, collaboration, and clinician support at their core (Armeni *et al.*, 2022)

2.4 Technological and Regulatory Readiness in India

Digital health involves using technology to collect and share health information so that patients and doctors can work together more effectively. India has been recognized internationally for its leadership in this area, such as initiating a World Health Organization resolution on digital health. India's National Digital Health Mission (NDHM), launched in 2020, aims to create a connected health system where every citizen has a unique health ID, enabling easier access to health services and records (Gudi *et al.*, 2021)

However, implementing digital health in India faces several challenges. Health governance is complicated because healthcare is managed at the state level, leading to differences in adoption and implementation. There is also a shortage of trained healthcare and health information professionals, especially in handling the new digital systems. Many digital tools currently

operate independently without easy sharing of information between platforms, which limits their usefulness. Privacy concerns around health data and lack of strong data protection laws also pose risks. Additionally, for digital health to succeed, people need to understand and trust the technology, which means more digital literacy and awareness programs are needed.

Despite these challenges, there are promising opportunities. With proper training of the workforce and better policies for managing health data, India can build a robust digital health ecosystem. The government's NDHM sandbox—a testing space for developers to build and integrate health applications—is an important step to encourage innovation and collaboration. Ultimately, digital health has the potential to reduce healthcare inequalities by providing services such as telemedicine, especially in areas with few doctors. The article highlights that with strategic planning, capacity building, and good governance, India can scale up digital health effectively to improve healthcare for all its citizens (Gudi *et al.*, 2021)

2.5 Gaps in the Literature and Justification for Current Study

While digital twin technology has been recognised for its potential in revolutionising healthcare and pharmaceutical development, there is a noticeable lack of region-specific research, particularly in the context of clinical trials conducted in India. Most existing studies focus on high-income regions like North America or Europe, where digital infrastructure and regulatory support are comparatively advanced (Kritzinger *et al.*, 2018). However, India presents a distinct set of challenges, including infrastructural constraints, regulatory differences, and a highly diverse patient population, making it essential to study the technology's applicability within this specific context.

Moreover, the literature reveals a gap in empirical research on implementation readiness. While theoretical frameworks highlight the benefits of digital twins—such as improved trial design, simulation capabilities, and real-time data monitoring—there is limited practical evidence on how ready the Indian clinical trial ecosystem is for adopting such technology. Important questions around cost, digital skills, interoperability, and regulatory alignment remain unanswered.

Another significant gap lies in the absence of stakeholder-based insights. Much of the available literature is developed from a technical or systems design perspective, often led by software developers or tech companies, rather than healthcare professionals or clinical trial managers (Fuller *et al.*, 2020). As a result, the voices of those directly involved in clinical trial operations—such as CRAs, trial coordinators, and regulatory experts—are largely missing from the discourse. Understanding their perspectives is crucial for identifying both the barriers and enablers of adopting digital twin solutions in practice.

This study aims to fill these gaps by gathering both qualitative data (via interviews with experienced clinical research professionals) and quantitative insights (via surveys). It will provide much-needed contextualised knowledge on digital twin adoption in Indian clinical trials, offering recommendations that are both realistic and grounded in the current clinical research environment. The study's findings could also support better planning, stakeholder engagement, and technology implementation strategies in future trials.

2.6 Summary and Link to Research Objectives

The literature reviewed for this study explored key themes central to understanding how digital twin technology could help reduce delays in clinical trials, particularly in the Indian context. It began by outlining the structure, stages, and known bottlenecks in clinical trial processes, highlighting that patient recruitment, retention, protocol design, and data monitoring remain persistent challenges. Studies consistently pointed to how delays in recruitment and high dropout rates contribute to rising costs, longer development timelines, and, in some cases, trial failure.

The review also examined how digital twin technology—originally designed for manufacturing and engineering—has now gained momentum in healthcare and pharmaceutical development. The core strengths of digital twins lie in real-time simulation, predictive analytics, and the ability to create virtual replicas of patients, which can be used to optimise trial planning and monitoring. Existing pilot projects in the U.S. and Europe have shown promising results in improving recruitment strategies, protocol design, and decision-making accuracy.

However, the review uncovered several gaps. First, there is a lack of India-specific studies that evaluate the readiness or suitability of digital twin adoption in clinical trials. Second, few studies include perspectives from frontline stakeholders such as clinical research associates, managers, or directors. Third, there is limited empirical data on the real-world application of digital twins in clinical settings.

These findings directly support the research aim, which is to explore how digital twin technology can address clinical trial delays in India. The literature also reinforces the research questions related to how digital twins influence trial efficiency, stakeholder perceptions, and the practical challenges of implementing such technology.

In conclusion, the literature review sets the stage for the next chapter—Research Methodology—by highlighting the need for both qualitative and quantitative insights to fill the identified knowledge gaps. This dual approach will ensure that the study provides a deeper, more grounded understanding of digital twin technology's role in transforming clinical trials in India.

2.7 Conceptual Framework

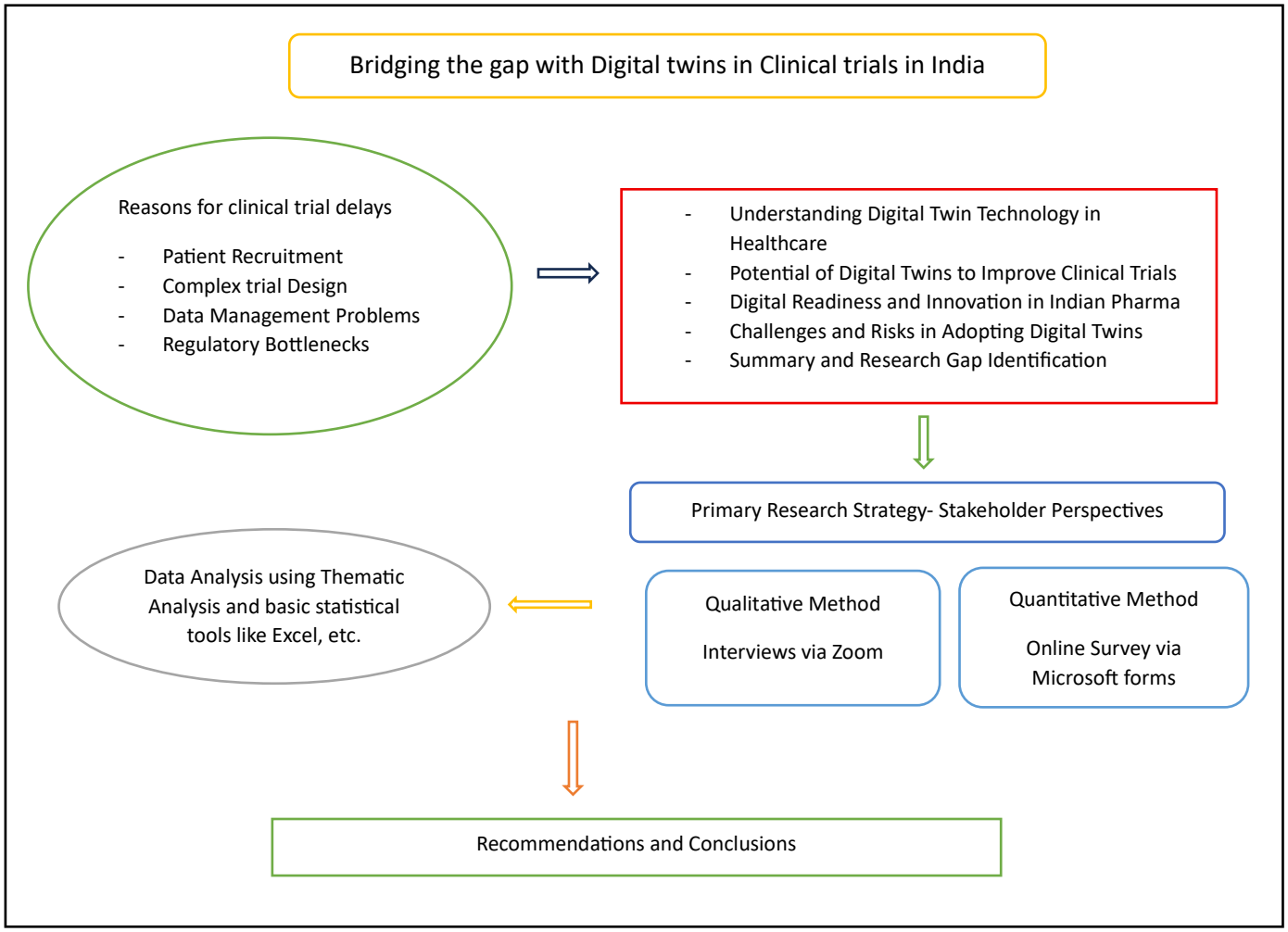

Fig. 13 Conceptual Framework for the proposed research (source: developed by Author)

Chapter 3
Research Methodology

RESEARCH METHODOLOGY

3.1 Overview of Research Methodology

Research is essentially about investigating a problem to uncover facts and draw new conclusions. Research methodology refers to the systematic approach used to solve a research problem (E V A Dissanayake, 2023). It lays the foundation for how the investigation is carried out and plays a crucial role in ensuring the credibility and reliability of the results. Different researchers may approach a problem from various angles, depending on their understanding of what constitutes valid research. This makes the careful selection of methodology essential to achieving meaningful and trustworthy outcomes (Ragab and Arisha, 2017).

There is no one-size-fits-all approach when it comes to research methodology. The choice depends largely on the topic, the nature of the research question, and the type of data being used. Therefore, it's important for researchers to be clear about the methodological path they choose and the philosophical assumptions behind it. Before collecting or analyzing data, they should evaluate the strengths and weaknesses of various methods, consider what best suits their specific project, and be ready to explain and justify their choices. Conducting research with this level of rigor ensures that the findings are not only valid but also transparent and well-supported (Ragab and Arisha, 2017)

To understand how digital twin technology can help reduce delays in clinical trials in India, this research adopts a pragmatic approach, combining both qualitative and quantitative methods. Pragmatism allows for flexibility in research design, helping to focus on real-world problems and practical solutions. Since digital twin use in clinical trials is still an emerging area—especially in the Indian context—it is important to capture both measurable patterns (through surveys) and in-depth professional experiences (through interviews). This mixed-methods strategy ensures a more complete picture, grounded in data as well as human insight. By combining both qualitative and quantitative types of data, this research hopes to not only identify if digital twins can help solve existing problems but also understand how ready the Indian clinical research environment is to adopt such a technology. The findings from both methods will be carefully analysed and compared to build practical, meaningful recommendations for the future of digital innovation in clinical trials.

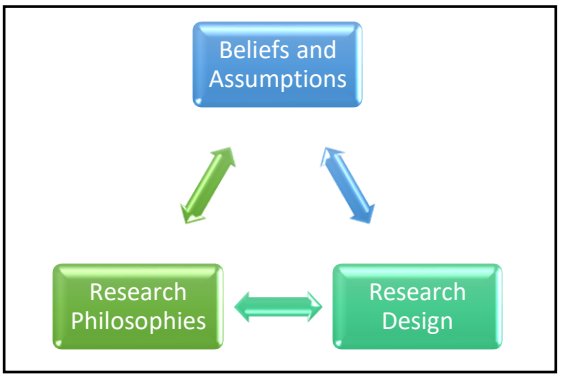

Fig. 14 Association between Research philosophy, Beliefs, and Research design (Saunders et al., 2019)

3.2 Research Design

Research design is a critical component of the research process, as it provides a structured framework for systematically collecting, analyzing, and interpreting data. It helps researchers clearly define their research questions, select an appropriate methodology, and choose the most suitable data collection techniques. To reflect the layered complexity involved in designing research, this study adopts the "research onion" model proposed by Saunders et al (Saunders *et al.*, 2019). This model offers a comprehensive framework that guides researchers through the various stages of research design, from philosophical foundations to practical data collection methods.

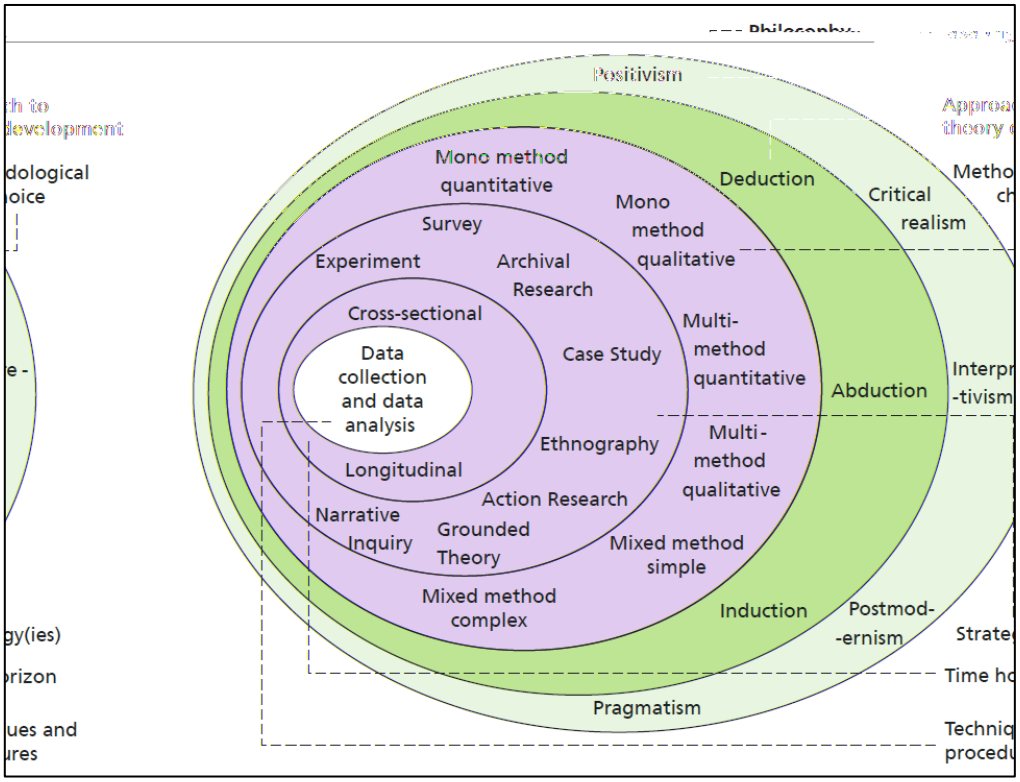

Fig. 15 Research onion as proposed by Saunders et al (Saunders et al., 2019)

To carry out a meaningful and structured investigation into how digital twin technology can reduce delays in clinical trials in India, it is important to follow a clear and logical research design. The "research onion" model by Saunders et al. provides a helpful framework that guides researchers through each stage of the research process—from philosophical underpinnings to data collection methods. By peeling back each layer of the onion, thoughtful decisions about the methods and strategies can be made that are best suited for this study. This layered approach allows for a well-rounded understanding of the topic, combining both practical and theoretical perspectives. In this research, each layer—from philosophy to technique—has been carefully chosen to align with the study's goals and the complexity of the topic. The following sections describe each of these layers in detail, explaining how they contribute to answering the research questions effectively.

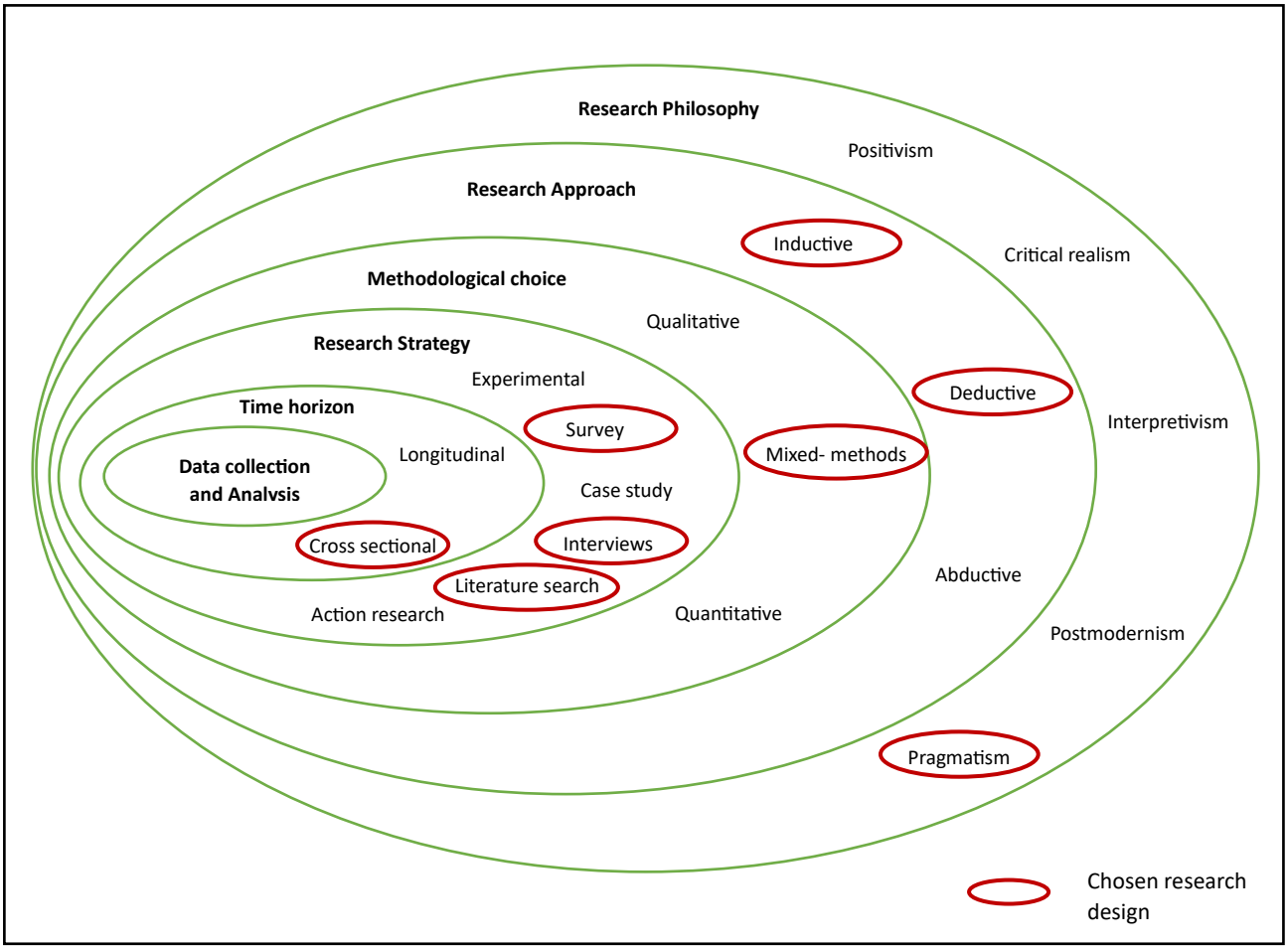

Fig. 16 Research onion for this research based on research onion by Saunders et al (source: developed by Author)

❖ Research Philosophy – Pragmatism

Pragmatism is the guiding philosophy for this research. This means the study focuses on practical outcomes and uses the best methods available to answer the research questions. Instead of committing to one strict worldview (like only numbers or only experiences), pragmatism allows combining both qualitative and quantitative methods. For the study, this is ideal because exploring both the measurable impact of digital twin technology in trials and also the opinions and experiences of professionals working in this area. It balances facts with lived experiences.

❖ Research Approach

For this study, a combined approach of both inductive and deductive reasoning has been adopted. This mixed approach allows the research to explore real-world experiences while also testing predefined ideas based on existing theories. By blending both approaches, the study benefits from the structure and clarity of deductive reasoning, while also remaining open to new insights through induction. This dual strategy ensures a more comprehensive understanding of how digital twins could transform clinical trials in the Indian context.

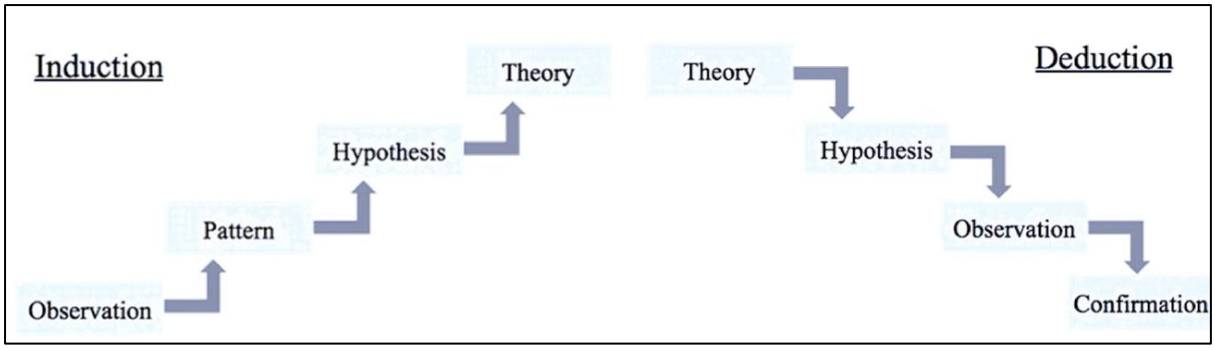

Fig. 17 Research Approach: Induction - and Deduction (Ragab and Arisha, 2017)

❖ **Research Choice – Mixed-Method**

This study uses a multi-method approach. That means it is collecting different kinds of data—qualitative from interviews and quantitative from surveys—but keeping them somewhat separate during analysis. This choice works well when each method serves a clear purpose in the overall research. In this case, interviews help explore the 'why' and 'how', while surveys focus on 'what' and 'how often'.

❖ **Research Strategy**

This research follows a mixed methods strategy, combining both primary and secondary research to explore how digital twin technology can help reduce delays in clinical trials in India. This approach ensures that the study captures both real-world insights and existing knowledge in a structured way.

Secondary Research: To build a strong foundation, secondary research was first conducted. This involved reviewing published academic journals, industry reports, government publications, and credible online sources related to clinical trials, digital twin technology, and the Indian healthcare landscape. The goal was to understand what has already been studied and where the gaps in current knowledge exist. This helped shape the research questions and design the primary research tools.

Primary Research: Primary research then carried out through two key methods: interviews and surveys.

- Interviews were conducted with experienced professionals from the clinical research field—such as Clinical Research Associates (CRAs), Trial Managers, and Regulatory Affairs specialists. These conversations provided in-depth, expert opinions and firsthand experiences about digital twins in clinical trials.
- Surveys were shared online with professionals in the industry to gather broader, quantitative data on trends, challenges, and the perceived impact of digital twin technology.

❖ **Time Horizon – Cross-sectional**

The study uses a cross-sectional time horizon, which means data is collected at one point in time rather than over months or years. This is appropriate given the 3-4 weeks' timeframe of the research. Even though digital twin technology and clinical trials evolve, this snapshot can still provide valuable insights into the current state of awareness, readiness, and challenges in India.

3.3 Sample Size Calculation

The sampling process plays a vital role in research methodology, as it directly impacts the accuracy and reliability of the study's findings. It begins by identifying the target population—this refers to the full group of individuals or entities that are relevant to the research question. Choosing the right sample ensures that the results are meaningful and reflective of the broader population the study aims to understand (Ahmed, 2024).

In research, participant selection is typically done through one of two main strategies: probability sampling and non-probability sampling. Each approach has its own strengths and limitations. Probability sampling ensures that every individual in the population has a known and non-zero chance of being selected, making it more statistically reliable. In contrast, non-probability sampling does not involve random selection, meaning some individuals may have no chance of being included. This method is often used when researchers face practical constraints, such as limited time, resources, or difficulty accessing the full population (Ahmed, 2024).

Qualitative Sampling (Interviews): For the qualitative component, the study includes semi-structured interviews with 8-10 experienced professionals working in clinical trials, including Clinical Trial Managers, CRAs, and Regulatory Affairs specialists. This purposive sample size is adequate to explore diverse expert insights in depth while allowing thematic saturation. In qualitative research, the goal is not generalization but understanding patterns, themes, and lived experiences—making 8-10 participants a sufficient and manageable number.

Quantitative Sampling (Survey): The survey is designed to gather broad perspectives from professionals working in clinical research roles such as Clinical Research Associates (CRAs), Trial Managers, Regulatory Experts, and others involved directly or indirectly in clinical operations in India. Since the target population is large and not precisely defined, we apply a sample size calculation for an infinite population using the standard formula by Cochrane (Ahmed, 2024)

Sample Size Formula (for large/undefined population):

$$N = \frac{Z^2 \times p \times (1-p)}{e^2}$$

Where:

- n = required sample size
- Z = Z-score (1.96 for 95% confidence level)
- p = estimated proportion of the population (0.5 used for maximum variability)
- e = margin of error (8% or 0.08)

Based on this calculation and substituting the values, the recommended sample size is approximately 150 participants. This size strikes a balance between statistical reliability and the practical feasibility of reaching busy professionals in the clinical trial ecosystem.

3.4 Participants in the study

This research involved two types of participants: those who completed the survey and those who participated in interviews. All participants were professionals currently working in the pharmaceutical or clinical research sector. These included Clinical Research Associates (CRAs), Clinical Trial Managers, Regulatory Affairs professionals, and other stakeholders involved in trial operations. Their practical experience and deep understanding of clinical processes made them ideal contributors to explore how digital twin technology could potentially reduce delays in clinical trials in India.

For the interviews, 10 participants were selected using purposive sampling. These individuals were chosen because of their senior roles and direct involvement in planning, monitoring, or overseeing clinical trials. Their insights helped uncover practical challenges and expectations surrounding the adoption of digital twin solutions. For the survey, approximately 150 participants from across India and were invited via LinkedIn, professional networks, and WhatsApp. This helped capture a broad perspective and allowed for quantitative analysis of common patterns and perceptions across the industry.

3.5 Inclusion and Exclusion Criteria

Inclusion criteria for this study included professionals currently working in clinical research, with at least two years of experience, and involved in any phase of clinical trial management—either directly or in a supporting capacity. Participants also needed to have a basic understanding of digital technologies used in clinical settings. Exclusion criteria included students, individuals with no professional experience in clinical trials, or those outside the pharmaceutical and life sciences domain. Participants without access to the internet or who were unable to give informed consent were also excluded.

This carefully selected group ensured that the study received relevant, insightful, and experience-based feedback, making the findings more applicable to real-world clinical research settings.

3.6 Access to Participants

Participants for this research were accessed primarily through professional networks, LinkedIn, and industry connections. Many of the interviewees were approached via mutual connections or colleagues from previous academic or workplace interactions. Using LinkedIn helped identify professionals actively involved in clinical research roles such as CRAs, Clinical Trial Managers, and Directors. A brief message explaining the research purpose and ethical assurance was sent to potential participants, inviting them to take part voluntarily. For the survey, the questionnaire was shared on professional platforms and WhatsApp, allowing for broader reach while still targeting relevant industry professionals. This approach ensured a diverse and experienced participant base, essential for gathering meaningful and credible insights.

3.7 Ethical considerations

This research has been designed with full respect for the rights, privacy, and well-being of all participants. Before taking part in the survey and/or interview, participants were provided with clear information about the purpose of the study, how their data would be used, and their rights as participants. Interview participants were asked to give signed informed consent, meaning they agreed to participate voluntarily after understanding the Participant Information Leaflet. They were also assured that they could skip any question or withdraw at any time without any consequences. No pressure was placed on anyone, and their participation was entirely voluntary. Survey participants had to select a consent checkbox before beginning the questionnaire, confirming that they had read the study information, understood the purpose of the research, and agree to take part voluntarily.

To protect privacy, all data collected was kept confidential and stored securely on a password-protected computer. No names or identifiable details will be shared in the final research report, and responses were anonymized during analysis. The study follows GDPR guidelines and the ethical standards set by the college. Overall, the research has been conducted responsibly, with care and consideration for every individual involved.

3.8 Structure of Interview Questions

The structure of the interview questions for this research was designed to be open-ended and exploratory, allowing participants to share their experiences, insights, and professional opinions in depth. The questions were grouped into key themes relevant to the study, such as their understanding and experience with clinical trials, awareness and use of digital twin technology, perceived benefits and challenges, and views on its potential impact on reducing delays in clinical trials in India.

This semi-structured format provided enough flexibility for participants to elaborate on topics they found important, while still ensuring that the core research objectives were addressed. Follow-up prompts were used when necessary to gain deeper clarity or examples. This approach helped capture rich qualitative data that reflects both industry trends and individual expertise.

3.9 Structure of Survey Questions

The survey questions in this research were structured to collect both quantitative and qualitative data in a simple and accessible format. They were designed to explore the awareness, understanding, and perceptions of professionals regarding the use of digital twin technology in clinical trials in India. The survey began with basic demographic questions to gather participant background (such as job role, experience level, and industry sector), followed by a mix of closed-ended and Likert scale questions to assess opinions on the benefits, challenges, and readiness for implementing digital twins in clinical research.

The questions were organised thematically—starting with general awareness of digital twin technology, moving into its potential applications in clinical trials (such as patient recruitment, monitoring, and protocol design), and finally gathering feedback on barriers, risks, and opportunities. Two final questions were included to ensure participants understood the study's purpose and voluntarily consented to take part. This structured approach allowed for efficient analysis while capturing meaningful trends and insights from a diverse group of professionals.

3.10 Data Analysis

For this research, both quantitative and qualitative data analysis methods were used to provide a balanced and comprehensive understanding of how digital twin technology can help reduce clinical trial delays in India. The mixed-methods approach ensured that numerical trends and deeper personal insights were both captured and analysed effectively.

3.10.1 Quantitative data analysis

Data was collected through structured survey questions, was analysed using descriptive and inferential statistical methods. Descriptive statistics such as percentages, median, and mode were used to summarise participant demographics, levels of awareness, and perceptions regarding digital twin technology. Inferential statistics, including chi-square tests and/or correlation analysis, were applied to explore relationships between variables such as job role and openness to adopting digital twins. The survey results helped identify common patterns, trends, and areas of concern among clinical research professionals, which support broader generalisations and decision-making. The survey tool Microsoft forms was used for initial data collection, followed by analysis in MS Excel for statistical interpretation.

3.10.2 Qualitative data analysis

This data was analysed using thematic analysis, a flexible method for identifying, analysing, and reporting patterns (themes) within the data. The interviews were transcribed, read repeatedly, and coded to highlight key insights related to the challenges, expectations, and practical experiences with digital twin technology. Emerging themes were organised around topics like implementation barriers, perceived benefits, regulatory concerns, and infrastructure readiness.

By combining both qualitative and quantitative analysis methods and presented in Chapter 4 of this research, the study offers a complete picture—both statistically grounded and experientially informed—on the readiness, potential, and concerns around digital twins in clinical trials within the Indian healthcare and pharmaceutical landscape.

3.11 Research Timelines

The research was conducted over a period of three months. The initial one month were dedicated to literature review and proposal development, followed by data collection through surveys and interviews over 3-4 weeks. The final phase involved data analysis, interpretation, and writing the dissertation**.**

3.12 Conclusion

In conclusion, this chapter outlined the research methodology adopted to explore how digital twin technology can reduce delays in clinical trials in India. A pragmatic approach was taken using a mixed methods strategy, combining both qualitative interviews and quantitative surveys. This methodology ensured a balanced understanding of both measurable impacts and personal insights. The ethical considerations, sampling strategies, and data analysis plans were carefully structured to ensure reliability and validity of the research.

Chapter 4
Finding and Analysis

FINDING AND ANALYSIS

4.1 Overview

This chapter presents and analyses the findings from both the survey and interview stages of the research. The aim is to explore how digital twin technology could help reduce delays in clinical trials in India by examining both measurable trends and personal experiences from industry professionals. Survey data is analysed to provide an overview of broader patterns and opinions, while interview responses are examined thematically to capture deeper insights into perceived benefits, challenges, and readiness for adoption. Together, these findings form the evidence base for the discussion and recommendations in the next chapter.

4.2 Qualitative Data Analysis

4.2.1 Participant Information

The interview participants for this study were professionals working in the field of clinical research and pharmaceutical development, selected for their direct experience and knowledge of clinical trial processes. More than 25 potential participants were contacted through professional networks, LinkedIn, and referrals, but only 8 agreed to take part in the interviews. Each of them was provided with clear information about the research purpose and process, and only those who voluntarily consented were included. This ensured that the voices captured in the interviews were both relevant and authentic, representing the perspectives of individuals actively engaged in or closely connected to clinical trial management. Anonymised participant information has been summarised in the table below.

Interviewee code	Professional Role	Years of Experience	Clinical experience in India
Interviewee 1	Clinical Research Associate	8 years	Worked extensively in cardiology, endocrinology, diabetes, and oncology trials; involved in all trial stages, from site selection to closeout.
Interviewee 2	Clinical Research Associate	6 years	Has experience in phase 2, 3, and 4 studies across vaccines, ulcerative colitis, COPD, and heart failure
Interviewee 3	Clinical Research Associate	6 years	Worked on phases 2–4 across oncology, surgical, and medical device trials.
Interviewee 4	Senior Clinical Research Associate	11 Years	Worked in oncology, cardiac, bone metabolism, and CKD trials, mainly in phases 3 and 4
Interviewee 5	Senior Clinical Research Associate	9 years	Worked across regulatory/start-up, central monitoring; has managed oncology, ophthalmology, neurology, and nephrology trials

Interviewee 6	Senior Clinical Research Associate	8 years	Managed trials across India, Africa, and the Philippines, with experience in vaccine studies (HPV, TB, rotavirus).
Interviewee 7	Senior Regulatory Affairs Specialist	7 Years	Regulatory experience, including oncology and ocular studies in phases 2–4, and currently manages global clinical regulatory submissions.
Interviewee 8	Clinical Research Associate	7 years	Experienced across oncology, ophthalmology, pulmonology, cardiology, dermatology, neurology, and psychiatry trials.

Table no. 1: Interview Participants Summary (source: developed by author)

4.2.2 Thematic Analysis of Interview Responses

Thematic analysis was employed in this research to systematically identify, organise, and interpret patterns of meaning within the interview data. This method enabled the extraction of recurring perspectives across interviewees, providing structured insights into the research objectives. Four core themes were selected based on both the literature and participant responses: *Delays in Clinical Trials in India: Causes*, *Perceived Benefits of Digital Twin Technology*, *Challenges and Barriers to Implementation in India*, and *Future Potential and Readiness for Adoption*. Each theme was divided into sub-themes, highlighting detailed viewpoints and connecting them to the study's objectives.

The analysis followed Braun and Clarke's six-phase framework (Ahmed *et al.*, 2025), beginning with familiarisation through repeated readings of the transcripts of recorded interviews. Initial codes were generated to capture meaningful segments related to trial delays, digital twin technology, and implementation barriers. These codes were then grouped into broader categories, allowing sub-themes to emerge inductively while also being guided by the predefined research objectives. Themes were carefully refined to make sure they were clear and distinct from each other. To improve reliability, coding was checked across several transcripts for consistency, and sub-themes were confirmed by comparing responses to see where views were similar or different. This process ensured that the final themes truly reflected the data and stayed aligned with the study's aims.

Thematic analysis was used in this study because it provides both flexibility and depth in understanding interviewee perspectives. Unlike grounded theory, which focuses on creating new theories, thematic analysis was more suitable for exploring and organising views within the context of existing research on clinical trials and digital technologies. Compared to content analysis, which mainly counts how often words appear, thematic analysis allows deeper interpretation of meaning and context. This made it the right approach for meeting the research goals, such as identifying causes of clinical trial delays, understanding awareness of digital twins, exploring their potential to reduce delays, and suggesting practical steps for implementation in India.

The themes and sub-themes linked to the research objectives, along with the interviewees' corresponding responses, are summarised in the table below.

Theme	Sub-theme	Linked Objective	Interviewees who responded
Delays in Clinical Trials in India: Causes	• Regulatory approvals and ethics committees • Site-level documentation and staff readiness • Patient recruitment challenges	Objective 1 (Identify & categorise causes of delays)	Interviewee 1 Interviewee 2 Interviewee 3 Interviewee 4 Interviewee 5 Interviewee 6 Interviewee 7 Interviewee 8
Perceived Benefits of Digital Twin Technology	• Protocol optimisation and trial simulation • Patient safety and adverse event prediction • Recruitment forecasting • Real-time monitoring and risk-based approaches	Objective 2 (Analyse current adoption status) Objective 3 (Evaluate potential to mitigate delay factors)	Interviewee 1 Interviewee 2 Interviewee 3 Interviewee 4 Interviewee 5 Interviewee 7 Interviewee 8
Challenges and Barriers to Implementation in India	• Limited awareness and expertise • High costs of deployment • Regulatory uncertainty • Infrastructure gaps • Resistance to change and Data integrity	Objective 2 (Analyse adoption status) Objective 4 (Propose framework for implementation)	Interviewee 1 Interviewee 2 Interviewee 3 Interviewee 4 Interviewee 5 Interviewee 6 Interviewee 7 Interviewee 8
Future Potential and Readiness for Adoption	• Adoption by global sponsors and large CROs • Regulatory frameworks as enablers • Training and capacity building	Obj. 3 (Evaluate potential) Obj. 4 (Propose framework & recommendations)	Interviewee 2 Interviewee 3 Interviewee 4 Interviewee 5 Interviewee 7 Interviewee 8

Table no. 2: Summary of Themes and sub themes in Qualitative Analysis (source: developed by author)

4.2.3 Results and Analysis

The thematic analysis results are presented under four main themes and sub-themes as mentioned in the table no. 2 that reflect the views of clinical research professionals. These themes, supported by sub-themes and direct quotes by interviewees, highlight key challenges affecting trial efficiency, such as regulatory delays and patient recruitment issues, while also showing the opportunities of digital innovations like digital twins. The findings reveal both common concerns and differing levels of awareness and readiness for digital twin adoption, linking professionals' real experiences to the research objectives.

4.2.3.1 Theme 1: Delays in Clinical Trials in India: Causes

A recurring theme across all interviews was the prevalence of delays in clinical trials in India, with interviewees consistently highlighting regulatory bottlenecks, site-level inefficiencies, ethics committee hurdles, and patient recruitment challenges. While each interviewee offered a unique perspective shaped by their role and experience, there was broad consensus that these delays not only slow trial timelines but also undermine India's ability to contribute meaningfully to global studies.

- Regulatory approvals and ethics committees

Most interviewees identified regulatory approval delays as a major cause. Interviewee 1 explained that "*Sometimes the approval process is a bit tedious. So that is one thing which can delay if you do not get the approval. within time or it gets delayed, then all your further milestones can get delayed*." Similarly, Interviewee 7 mentioned *"as per the checklist which is to be submitted to the DCGI, it's like two months goes in collecting data and then after submission it takes almost four to six months for DCGI approvals, and delay the application review and approval."* Interviewee 5 echoed this by noting that *"often, when approvals finally come, the global recruitment is already over, and India loses its chance."* These responses illustrate how systemic inefficiencies in national and institutional review boards slow trial progress.

- Site-level documentation and staff readiness

Several interviewees pointed to site-related bottlenecks. Interviewee 3 observed and said that *"it will depend upon the site, how experienced the site is to get on starting of the clinical trials. But it has many numbers of aspects regarding the documents also….."* while Interviewee 6 stressed the impact of paper-based processes: *"remote areas (in India) where the network is not strong and the sites are still very much used to using paper, which then creates delay because there's data entry that needs to happen."* Interviewee 8 added that logistics, protocol amendments, and even payment issues at closeout all contribute to unnecessary lags by saying *"there are delays because of the supplies not properly or in timely manner dispatched to sites because of which we cannot initiate the study at the site……"* These operational challenges highlight how trial conduct is hampered at the execution level.

- Patient recruitment challenges

Recruitment was another universally cited barrier. Interviewee 7 stated that *"it (a study) was approved for conducting trials in India but due to lack of patient recruitment it got dropout and it wasn't completed further…."* Interviewee 2 similarly noted *"low patient recruitment rates, which often leads to delays in clinical trial initiation. Then this low patient recruitment also results into participant hesitation to take part in the clinical trial…."* Interviewee 4 pointed out how cultural and communication barriers exacerbate the problem and also mentioned that "*if we don't start on time, then there's a chance that we might not get the patients that we are requiring for that particular indication,,,"*

In summary, all eight participants agreed that regulatory approvals and patient recruitment are the most significant delay factors, with Interviewee 1, Interviewee 5 and Interviewee 7 particularly focused on regulatory misalignments, while Interviewee 2, Interviewee 4 and Interviewee 8 emphasised recruitment issues. Interviewee 3 and Interviewee 6 highlighted site

inefficiencies, and Interviewee 8 provided a more holistic breakdown, covering delays across all phases of the trial lifecycle.

Theme 1 showed that delays in clinical trials in India are mainly caused by regulatory bottlenecks, ethics committee backlogs, site inefficiencies, and patient recruitment challenges. Participants agreed that slow approvals from DCGI and ethics committees delay trial initiation, while manual processes and poor site management add to the problem. Recruitment was a common concern, with strict eligibility criteria, patient dropouts, and low awareness making it harder. Suggested solutions included digitalising approvals and documentation, aligning regulations with global standards, improving site training, and engaging patients better. Overall, the findings pointed to both structural and operational delays, along with a clear need for reform to make India more competitive in global trials.

4.2.3.2 Theme 2: Perceived Benefits of Digital Twin Technology

While awareness of digital twin technology varied among participants, all interviewees recognised its potential benefits once the concept was explained. Responses focused around five perceived advantages: protocol optimisation, recruitment forecasting, patient safety, cost reduction, and real-time monitoring.

- Protocol optimisation and trial simulation

Several participants viewed digital twins as a way to strengthen trial design before implementation. Interviewee 4 reflected that *"....try to have a common protocol across all countries. So this (digital twin) technology can be utilized to analyze the way of working in different countries. And maybe they can come into a common ground where they can design a protocol which can, you know, work in all the countries.."* Interviewee 5 echoed it by saying, *"it can be used for protocol design, which is very common for all the population across the globe.."* Interviewee 8 also suggested *"there are some criteria which usually medical writers use, when they design the protocol; so this (digital twin) can help them to design protocol which will be patient friendly"*

- Patient safety and adverse event prediction

Few interviewees noted safety-related benefits. Interviewee 1 saw this as particularly valuable in high-risk therapeutic areas, noting *"That (digital twins) would be a really helpful way to reduce the side effects and think about how efficiently we can use the molecule"* and stated that oncology trials could benefit from early risk identification through twin simulations. Interviewee 3 remarked that *"even we will be able to, what you can say, analyze the safety potential, safety concerns of the patient if you are doing a particular clinical trial."*

- Recruitment forecasting

Many respondents highlighted recruitment as an area where digital twins could have significant impact. Interviewee 2 pointed out that *"this can be used to predict the outcomes and trial interventions in the clinical trial. without physically conducting the procedures or the actual participation."* Interviewee 7 reinforced this, stating *"I think that gap can be fulfilled by these digital twins where there are less patients; areas where the clinical trials are lacking, like the sufficient number of patients to have a proper stable data to conclude some result."* Interviewee 4 suggested that *"If I say patient recruitment, basically I wanted to see how this particular tech*

can help me to target the cities or, you know, the parts of India where I can find the particular patient pool."

- Real-time monitoring and risk-based approaches

Lastly, some interviewees highlighted digital twins' role in monitoring. Interviewee 6, for example, suggested *"for processes that happen post the data capture, so post any communication with the subject, after that, whatever happens to that data, the analysis, the review, digital twins in that I think will help and really fasten the process and make it error less error prone"* Interviewee 8 also mentioned *"So remotely, instead of going at the site, remotely I can with this technology, review this data by sitting at my office or at my home and I can monitor the data.."* Interviewee 1 also added "*We can have a risk-based monitoring with the use of digital twins basically based on the challenges which are seen in the other studies and the data which is available can foresee the challenges.."*

Although interviewees varied in familiarity with the technology—some interviewees had only recently encountered the concept—they all recognised clear benefits once it was explained. Interviewee 4, Interviewee 5, and Interviewee 8 emphasised protocol design and simulation; Interviewee 2, Interviewee 7 and Interviewee 4 highlighted recruitment forecasting; Interviewee 3 and Interviewee 1 focused on safety; while Interviewee 1, Interviewee 6 and Interviewee 8 stressed monitoring and efficiency. Overall, participants agreed that digital twins offer multi-dimensional value, especially in addressing trial delays related to protocol amendments, recruitment, and monitoring.

Analysis of Theme 2 showed that interviewees viewed digital twin technology as a powerful tool with multi-dimensional benefits for clinical research. Once familiar with the concept, interviewees identified its potential to optimise trial protocols, simulate outcomes, and forecast recruitment bottlenecks, thereby reducing costly amendments and delays. Several interviewees also highlighted its role in enhancing patient safety through early detection of adverse events and improving efficiency by enabling real-time monitoring and risk-based oversight. While perspectives varied depending on professional experience, there was strong consensus that digital twins could accelerate trial timelines, lower costs, and provide sponsors with more reliable data for decision-making.

4.2.3.3 Theme 3: Challenges and Barriers to Implementation of Digital Twins in India

While interviewees recognised the potential of digital twin technology, they were equally candid about the challenges and barriers to its adoption in the Indian clinical research ecosystem. The most prominent concerns were high implementation costs, lack of awareness and expertise, regulatory uncertainty, infrastructure gaps, and cultural resistance to change.

- Limited awareness and expertise

A recurring theme was the lack of technical understanding among professionals. Interviewee 1 stated that *"India needs to be little bit more advanced to adopt technology, I would say and lack of training and technology advancement especially in the rural area wherever network is the biggest issue."* Interviewee 4 added that *"if it's too technical, not so easy to understand, so definitely there will be a pushback from the team, from the people since it's very difficult to understand these kinds of technologies."* Interviewee 7 also mentioned that *"if we are using*

digital twins we need to consider two-three scenarios like the geographical area and the emotional factors of people which are the current challenges of India that happens at the site level"

- High costs of deployment

A couple of interviewees emphasised the financial burden. Interviewee 2 stated that *"Probably the high cost of implementation and integration into the existing system."* Similarly, Interviewee 3 noted that *"most of the companies will go for the cost if it is a costlier tool and then they will think what you can say twice before implementing it"*

- Regulatory uncertainty

Regulatory ambiguity was another major barrier. Interviewee 8 pointed out that *"Indian regulations because we need to have that kind of regulations that are there in our in our country so that might be affected."* Interviewee 5 echoed this concern, stating *"I am thinking is regulatory acceptance. Regulatory authorities are taking time to accept the plain and simple protocol. Explaining it to them is a challenge. So, first train them and then introduce in India.."*

- Infrastructure gaps

Infrastructure limitations, particularly in smaller cities and rural hospitals, were also raised. Interviewee 6 explained that *"many of our studies are done in remote places where otherwise training them for accepting the digital infrastructure is a challenge."* Interviewee 8 noted the disparity between global and local readiness: *"big pharma and global CROs may adopt it, but Indian sites will lag behind."*

- Resistance to change and Data integrity

Finally, cultural and behavioural resistance were identified as barriers. Interviewee 2 remarked that *"limited awareness of the people or expertise in this kind of model and lack of training of the people and the most common will be I think the resistance to change in a traditional trial workflow system…."* Interviewee 6 added that "*the most uh common problem is any institution so whether it be the hospitals or the health centres where usually these clinical trials are done them accepting any technology is still a challenge."* Interviewee 3 added that on data integrity by saying *"if you consider particularly like ethical consideration, like consent, like data privacy is one of the biggest challenges…"* Interviewee 5 mentioned that *"if the digital twin will be launched in India, I should say the security will be apt. privacy and security should be taken care of… so the patient confidentiality matter and access should be given only to doctor to protect the patient privacy"*

All interviewees recognised multiple barriers, but with varying emphasis. Interviewee 2 and Interviewee 3 highlighted costs whereas Interviewee 5 and Interviewee 8 highlighted regulatory gaps; Interviewee 1, Interviewee 4 and Interviewee 7 stressed awareness and training challenges; while Interviewee 2, Interviewee 3, Interviewee 5 and Interviewee 6 discussed resistance to change. Collectively, these perspectives underscore that while digital twin technology is promising, its implementation in India will face layered structural, cultural, and economic challenges.

The analysis of Theme 3 revealed significant challenges to implementing digital twins in India, ranging from high costs of deployment and limited technical awareness to regulatory ambiguity

and infrastructure gaps. Participants consistently pointed to financial constraints as a barrier, especially for smaller CROs and sites, and stressed the lack of training and understanding among staff. Regulatory uncertainty emerged as another critical factor, with respondents highlighting the absence of clear DCGI or ICMR guidelines. Resistance to change and reliance on traditional paper-based systems were also seen as cultural barriers. Overall, while participants acknowledged the potential of digital twins, they agreed that successful adoption in India would require investment, regulatory clarity, workforce training, and gradual digitalisation of site operations.

4.2.3.4 Theme 4: Future Potential and Readiness for Adoption

Despite the challenges identified, interviewees expressed cautious optimism about the future of digital twin technology in India. Their responses suggested that while adoption may be slow and incremental, larger CROs and global sponsors are likely to drive readiness, supported by regulatory evolution, digitalisation trends, and capacity-building initiatives.

- Adoption by global sponsors and large CROs

Several respondents felt that multinational companies would be the first to bring digital twin technology into India. Interviewee 7 stated that "*if there are like reference countries such as US, Japan, Canada if they are implementing these digital twins, there then the India government like the DCGI can take it as a reference, a good reference of how beneficial it can be…"* Interviewee 4 *mentioned "Because, you know, see the world keeps on changing, when you have such kind of technology, it's better to take a feedback from the global market"*

- Regulatory frameworks as enablers

Regulation was seen as a key determinant of readiness. Interviewee 4 emphasised that *"Regulators are open with the technology. If you look at the current ICH-GCP E6 R3, which has come in July 2025, if you go through it, you will see that a lot of technological insights have been added."* Interviewee 2 *echoed this, stating "develop a clear regulatory guidance system around the digital twins' usage in the clinical trial."* Interviewee 8 added by saying "*I will suggest of first having a clear regulations or clear guidance to implement such kind of technology."* Interviewee 3 suggested "*I recommend implementing legitimacy if it is coming from the regulatory perspective so that will create a transparency and everyone will implement and standardize this technology*."

- Training and capacity building

Several Interviewees stressed the importance of workforce readiness. Interviewee 6 observed that "*if a client expects us (CRO) to do something, then automatically the trainings that are required for that process, you know, all of that automatically will come into our scope of work and then eventually automatically we will also train the sites and the subjects*." Interviewee 8 added that "*so the training should be properly given to whoever is involved in the trial so that there would be no loss of data and privacy is maintained."*

Across participants, there was broad agreement on the long-term potential of digital twins, though with varying levels of optimism. Interviewee 7 and Interviewee 4 highlighted the role of global sponsors and digitalisation trends; Interviewee 2, Interviewee 3, Interviewee 4 and

Interviewee 8 pointed to regulatory clarity as the main enabler; Interviewee 6 and Interviewee 8 focused on training and change management. Collectively, the responses suggest that while readiness in the short term is limited, the medium- to long-term trajectory is positive, with India expected to gradually integrate digital twins into its clinical trial ecosystem.

Theme 4 highlighted cautious optimism among participants regarding India's readiness to adopt digital twin technology. Respondents believed that global sponsors and large CROs would lead initial adoption, with Indian sites following as part of global trials. Growing digitalisation trends, such as increased use of electronic data capture and remote monitoring, were seen as indicators of progress. Many stressed the importance of regulatory frameworks and training to build confidence among stakeholders. While short-term readiness was considered limited, participants anticipated a positive trajectory in the medium to long term, with India gradually aligning to global standards and potentially emerging as a strong player in digital clinical trials within the next decade.

In conclusion, the thematic analysis showed that clinical trials in India face major delays due to regulatory bottlenecks, site inefficiencies, and patient recruitment issues. However, interviewees saw potential in digital twin technology to help solve these problems through simulation, optimisation, and predictive modelling. Key barriers like high costs, low awareness, regulatory uncertainty, and lack of infrastructure still limit adoption. Even so, the outlook was cautiously positive, with interviewees expecting that global sponsors, evolving regulations, digitalisation, and better workforce training will gradually support the use of digital twins and strengthen India's role in global clinical research.

4.3 Quantitative Data Analysis

The survey data was analysed using descriptive and inferential statistics to identify trends, patterns, and relationships among responses. This helped quantify professionals' views on clinical trial delays and the potential of digital twin technology. The results provided measurable insights that complemented the qualitative findings from interviews.

4.3.1 Understanding of research Purpose

The first question of the survey asked participants if they had read and understood the purpose of the research, which focuses on how digital twin technology can reduce clinical trial delays in India. Out of 149 respondents, 145 (97%) said they understood the purpose, while only 4 (3%) did not. This shows that the study's aim was communicated clearly and effectively. Since the 4 respondents who did not understand may not provide reliable answers, their responses would be excluded from further analysis. Overall, this high level of understanding adds to the reliability and credibility of the survey results. To illustrate this, the distribution of responses is shown in the pie chart below.

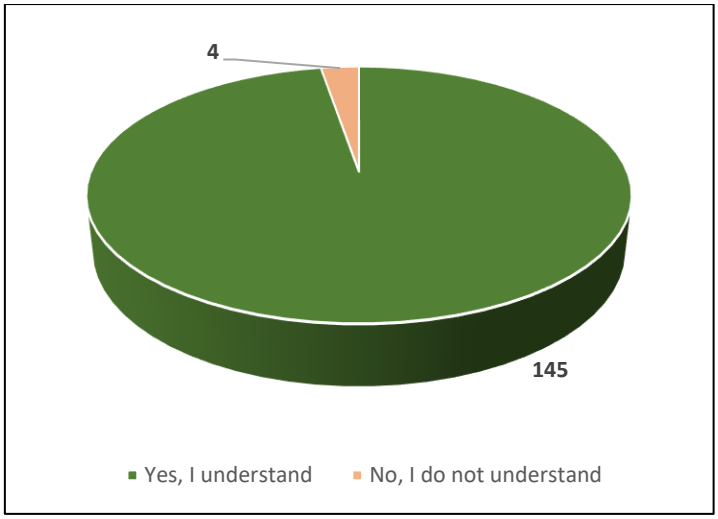

Fig. 18 Participants' Understanding of Research Purpose

4.3.2 Participant Consent

The second question sought to confirm whether participants voluntarily consented to take part in the research, acknowledging confidentiality and the option to withdraw at any time without consequences. Out of the 145 valid respondents (after excluding the 4 participants from Question 1 who did not understand the research purpose), 100% (145 participants) gave their consent, while 0% (0 participants) withheld consent. The unanimous consent among the 145 valid respondents highlights a strong willingness to engage in the study. This outcome reflects participants' trust in the confidentiality measures and their acceptance of the ethical safeguards communicated in the survey. Since every valid respondent agreed to participate, no further exclusions are required at this stage. This ensures that the dataset used for analysis is based entirely on voluntary and ethically valid participation, strengthening the reliability of subsequent findings. The responses are shown in the pie chart below.

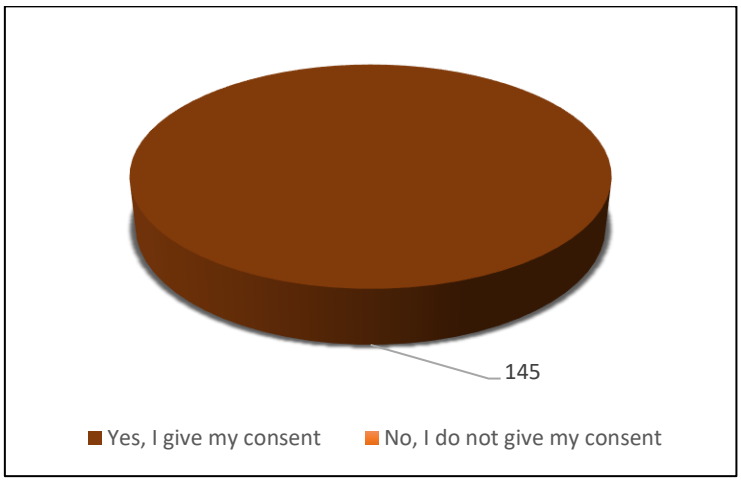

Fig. 19 Participants' consent

4.3.3 Demographics

4.3.3.1 Participants' current professional role

To better understand the professional background of respondents and the diversity of perspectives represented, participants were asked to share their current job title or role within the clinical research or pharmaceutical industry. The responses are represented in the bar graph provided below.

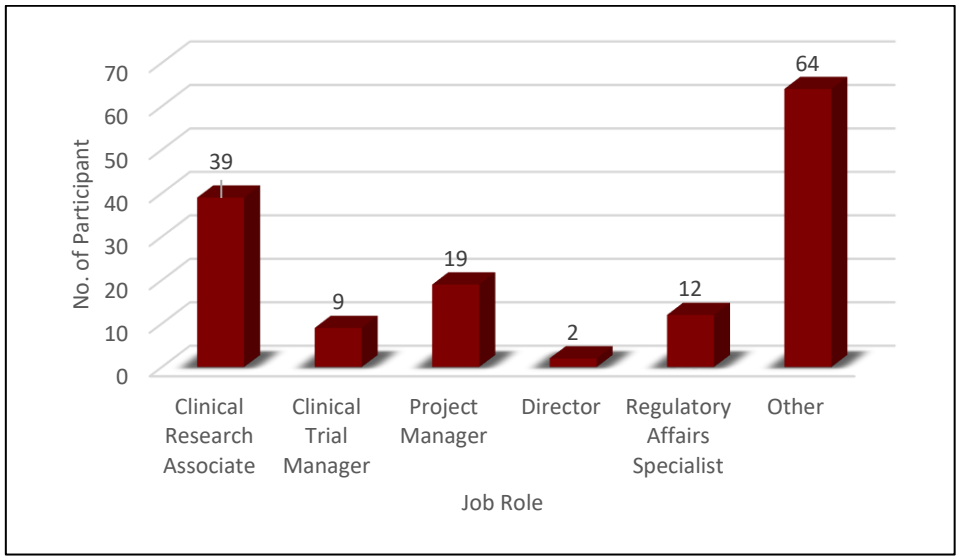

Fig. 20 Participant's current Job profile

The distribution of job roles as shown in the graph above highlights that nearly half of the respondents (44.1%) identified themselves under the "Other" category. A closer look at this group reveals positions such as Digital Asset Management, Learning & Development Specialist, Senior Director, Associate Director- Clinical Procurement, etc. which extend the scope of perspectives represented in this study. Among the predefined categories, Clinical Research Associates form the largest share (26.9%), followed by Project Managers (13.1%). Smaller segments include Regulatory Affairs Specialists (8.3%), Clinical Trial Managers (6.2%), and Directors (1.4%). The inclusion of senior-level roles (e.g., Senior Director, Associate Director) alongside operational and specialised functions such as digital asset management and procurement demonstrates the wide-ranging professional engagement in the survey. This diversity strengthens the dataset by ensuring that insights are captured from both strategic decision-makers and hands-on clinical research professionals, offering a comprehensive view of industry perspectives.

4.3.3.2 Participants' year of experience in clinical or pharmaceutical industry

The fourth question captured the level of professional expertise among respondents where the participants were asked to indicate the number of years they have worked in clinical research or the pharmaceutical industry.

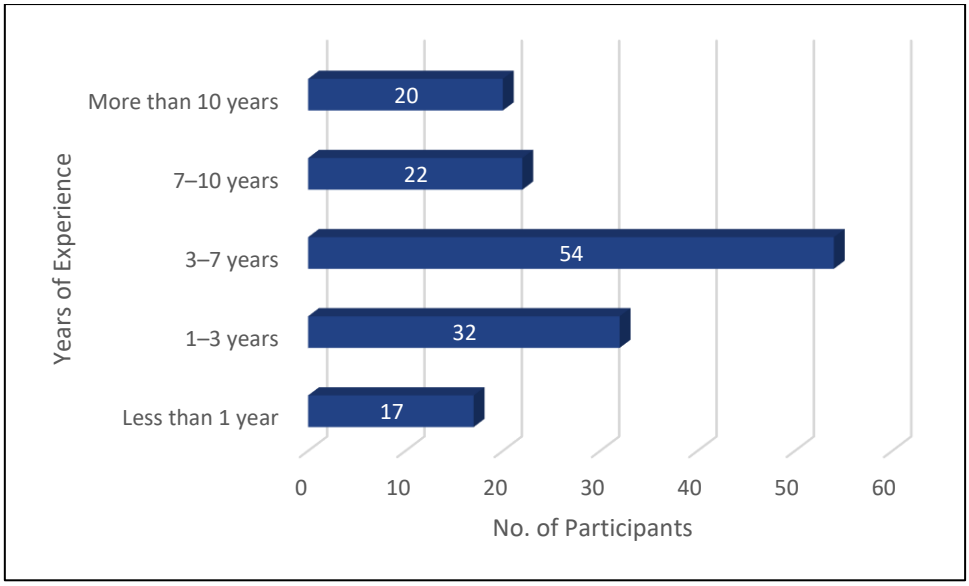

Fig. 21 Participant's years of experience

The results as presented in the bar chart above shows that that the largest group of participants has 3–7 years of experience, with 54 respondents (37.2%), highlighting that a significant portion of the sample represents mid-career professionals with solid industry exposure. This is followed by 32 respondents (22.1%) in the 1–3 years range, reflecting a sizeable early-career cohort. Smaller but important groups include 22 participants (15.2%) with 7–10 years of experience and 20 participants (13.8%) with more than 10 years, representing more senior professionals. Finally, 17 respondents (11.7%) reported having less than 1 year of experience, indicating the presence of newer entrants to the field. Overall, this balanced distribution across different experience levels enriches the dataset, ensuring insights from both junior and senior professionals are captured, thereby adding depth and credibility to the study's findings.

4.3.3.3 Participants' current work organization

Participants were asked to specify the type of organization they are currently working with, in order to understand the diversity of professional settings represented in the study.

The majority of respondents reported working in pharmaceutical companies, with 66 participants (45.5%), followed by 45 participants (31%) from Contract Research Organizations (CROs). Together, these two categories account for more than three-quarters of the sample, underscoring the strong representation of the core stakeholders in clinical trial execution and oversight. A smaller group of 14 respondents (9.7%) represented hospitals, contributing insights from the healthcare delivery side of clinical research. Regulatory authorities were minimally represented, with only 2 participants (1.4%), reflecting limited input from policy and oversight perspectives. The following pie chart presents the responses.

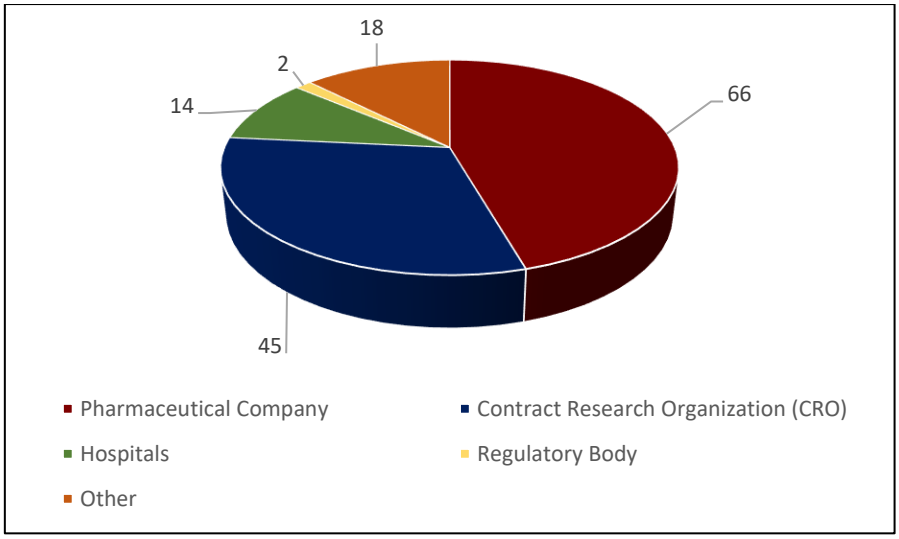

Fig. 22 Participants' current work organisation

The "Other" category, comprising 20 respondents (12.4%), included a diverse range of organisations such as Clinical Trial Units (Academic Research Organizations), Market Research/CRO, Healthcare Logistics and Transportation, Healthcare Advertising, etc. The inclusion of these roles highlights the wider ecosystem that supports clinical research beyond traditional pharmaceutical and CRO structures. This distribution demonstrates that while the dataset is strongly anchored in industry stakeholders, it also incorporates perspectives from allied sectors that play critical roles in trial management, logistics, and communications, thereby enriching the comprehensiveness of the study.

4.3.3.4 Participants' experience with Clinical Trials in India

This section presents the responses of participants regarding their experience working on clinical trials directly or indirectly in India.

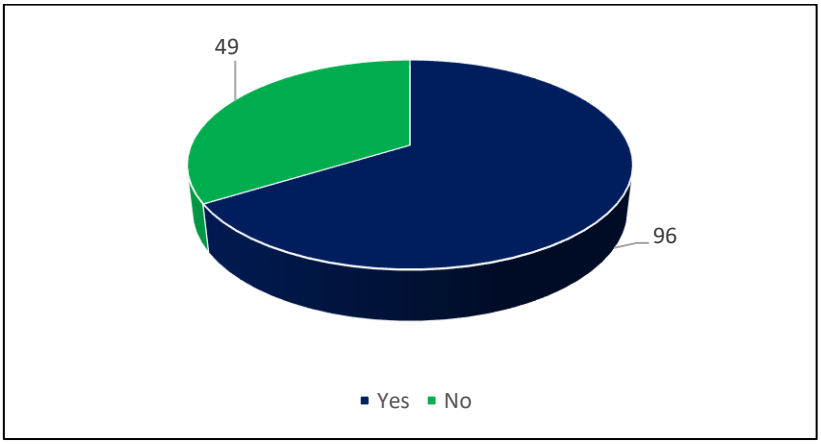

Fig. 23 Participants' Clinical trial experience

The results presented in pie chart above indicate that a clear majority of respondents, 96 participants (66.2%), reported that they have directly worked on clinical trials in India. In

contrast, 49 participants (33.8%) indicated "No," meaning that they have been involved indirectly in clinical trials or has knowledge of clinical trials in India, possibly through supportive, administrative, or related roles. This distinction highlights that while most participants bring direct operational experience from Indian clinical trials, a substantial proportion still provide valuable insights from indirect contributions within the broader clinical research ecosystem. The inclusion of both direct and indirect experiences ensures that the dataset captures diverse perspectives, from those managing trials on the ground to those supporting them through ancillary functions such as logistics, data management, or policy-related work.

4.3.4 To identify and categorize the primary causes of clinical trial delays in India

4.3.4.1. Top causes of delays in clinical trials in India

To better understand the challenges in the Indian clinical research landscape, respondents were asked to identify the top causes of delays in clinical trials based on their professional experience. The funnel chart below outlines the responses.

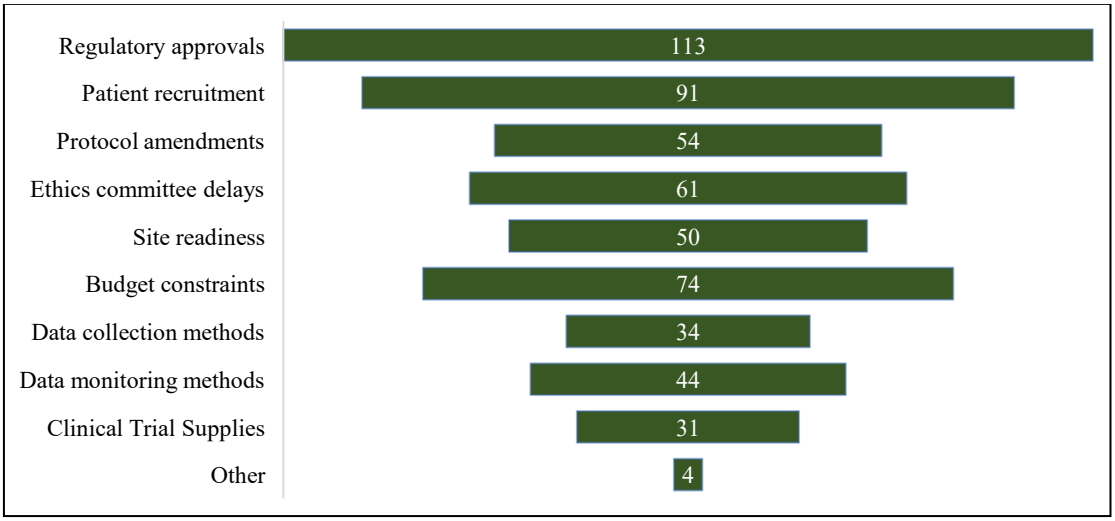

Fig. 24 Participants' response to delays in clinical trials

The findings show that regulatory approvals were overwhelmingly identified as the top cause of clinical trial delays, with 113 respondents (77.9%) selecting this option. This highlights the significant bottleneck posed by lengthy or complex approval processes in India. The next most frequently cited factors were patient recruitment, chosen by 91 respondents (62.8%), and budget constraints, selected by 74 respondents (51%), indicating that operational and financial challenges are also widely experienced.

Mid-ranked causes, represented by the median, include protocol amendments with 54 respondents (37.2%) and site readiness with 50 respondents (34.5%), suggesting that trial adjustments and institutional preparedness contribute to delays, though not as consistently across all respondents. Other challenges such as ethics committee delays (61 respondents, 42.1%), data monitoring methods (44 respondents, 30.3%), data collection methods (34 respondents, 23.4%), and clinical trial supplies (31 respondents, 21.4%) were reported less frequently but still represent noteworthy barriers. Only 4 respondents (2.8%) identified "other" causes, which likely refer to context-specific logistical or administrative issues.

In summary, the mode of the data, regulatory approvals (116 respondents, 80.6%), identifies the most pressing and universally acknowledged barrier, while the median causes—protocol amendments (55 respondents, 38.2%) and site readiness (50 respondents, 34.7%)—highlight mid-level challenges that reflect an average perception across participants. Together, this distribution indicates that while regulatory and recruitment issues dominate, multiple operational and infrastructural factors collectively contribute to clinical trial delays in India.

4.3.4.2. Seriousness of delays in clinical trials in India

Respondents were asked to rate how serious they consider clinical trial delays to be in India based on their professional experience to assess the perceived magnitude of the issue.

The results presented in bar graph show that the majority of participants perceive clinical trial delays in India as a moderate to significant challenge. The largest group, 62 respondents (42.8%), rated delays as moderately serious, while 43 respondents (29.7%) considered them very serious. Together, these two categories account for nearly three-quarters of the total sample (72.5%), highlighting that delays are widely acknowledged as a pressing issue. Smaller proportions of participants regarded delays as slightly serious (27 respondents, 18.6%) or not serious (8 respondents, 5.5%). Only 5 respondents (3.5%) felt that delays were extremely serious, suggesting that while delays are recognised as problematic, relatively few perceive them as a crisis-level concern.

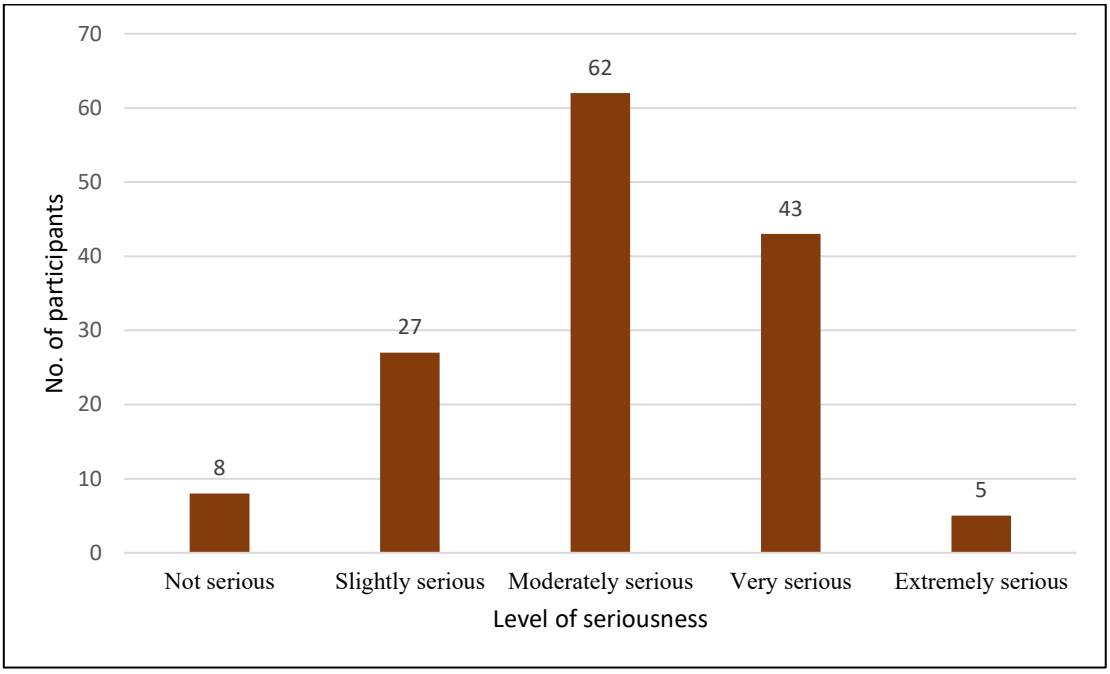

Fig. 25 Seriousness levels for delays in clinical trials

The distribution of responses indicates that the data is negatively skewed (left-skewed). This is because the majority of responses are concentrated toward the higher seriousness categories (moderately, very, and extremely serious), while fewer participants selected the lower seriousness options (not serious, slightly serious). In negatively skewed data, the tail of the distribution extends more to the left, which is consistent with this result since very few respondents rated delays as "not serious."

4.3.5 Analyze the current awareness and adoption status of digital twin technology in the clinical research sectors of India

4.3.5.1 Awareness of Digital twins

To assess the level of awareness, respondents were asked whether they had heard of the term 'Digital Twin' in the context of clinical trials prior to participating in this survey.

The results indicate that awareness of the concept of "Digital Twin" in clinical trial contexts is split among participants. Exactly half of the respondents, 74 participants (51%), reported that they had heard of the term prior to this survey. Meanwhile, a substantial proportion, 59 respondents (40.7%), stated that they had not encountered the term, and a smaller group of 12 respondents (8.3%) were unsure. This distribution shows that while there is a considerable level of familiarity with digital twin technology among clinical research professionals, a significant knowledge gap still exists. The nearly balanced divide suggests that awareness is emerging but not yet widespread, which has implications for adoption, training, and industry readiness in India. The following donut pie chart presents the responses.

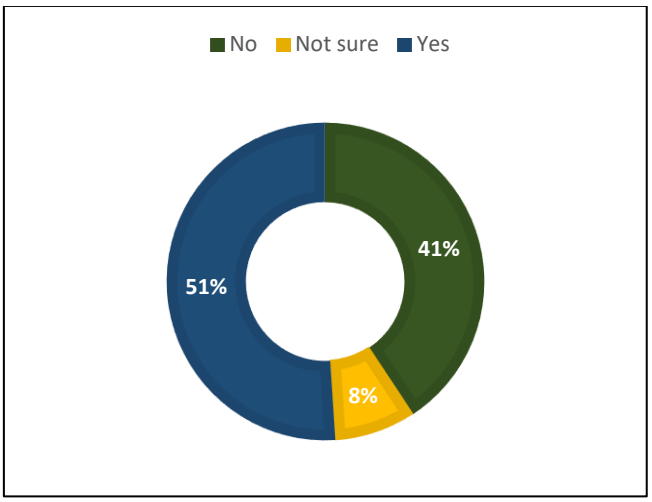

Fig. 26 Participants' level of awareness of Digital Twins

4.3.5.2 Level of Familiarity of Digital Twins

To gauge the depth of knowledge beyond basic awareness, respondents were asked to indicate how familiar they are with the concept of Digital Twins in the context of clinical research.

The findings reveal that familiarity with the concept of Digital Twins in clinical research is still relatively limited among professionals. The largest group, 51 participants (35.2%), indicated they are not at all familiar with the concept, while 46 participants (31.7%) described themselves as only slightly familiar. On the other hand, 31 respondents (21.4%) reported being moderately familiar, suggesting a smaller but notable group with some understanding of the concept. Only 16 participants (11%) described themselves as very familiar, and just 1 participant (0.7%) considered themselves extremely familiar. This distribution shows that while a few professionals are well-informed, the concept has not yet achieved widespread penetration within the industry.

The results as shown in the graph underline the need for greater awareness-building and training initiatives if Digital Twin technology is to be more effectively adopted in clinical

research, especially in contexts such as India where digital transformation is still at a growing stage.

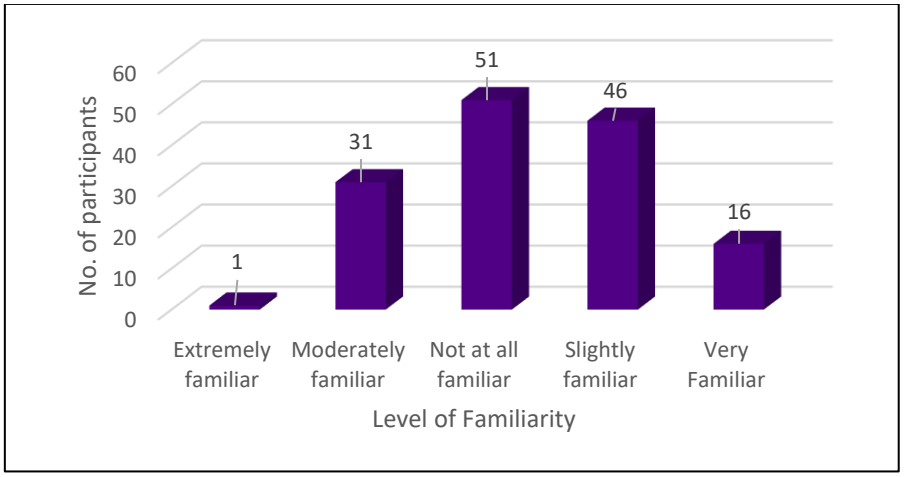

Fig. 27 Participants' level of familiarity with Digital Twins

4.3.5.3 Adoption status of digital twin technology in the clinical research sectors of India

To evaluate industry readiness, respondents were asked whether they believe India's clinical trial sector is prepared to adopt digital twin technology. The pie chart below provides a visual representation of the responses.

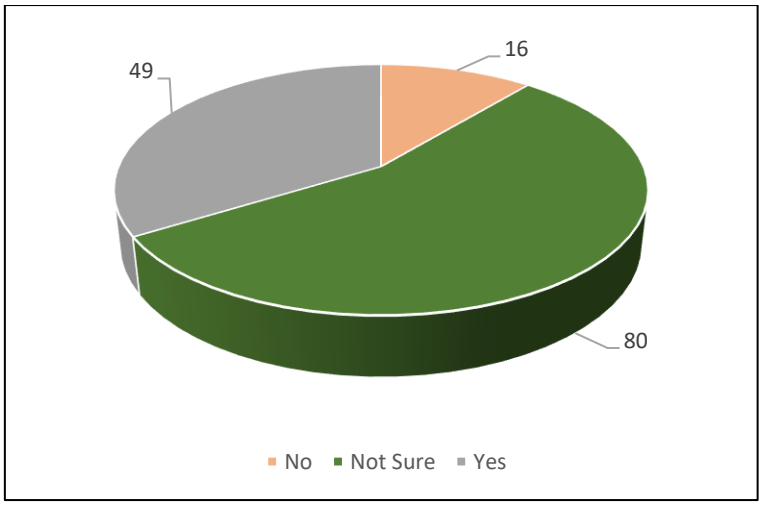

Fig. 28 Adoption status of Digital twins in clinical trials in India

The results suggest that there is a high degree of uncertainty regarding India's readiness to adopt digital twin technology in clinical trials. A majority of participants, 80 respondents (55.2%), reported that they were not sure about the industry's preparedness. This indicates that awareness of digital twin applications may not have translated into a clear perception of implementation feasibility within the Indian clinical trial environment. Meanwhile, 49 respondents (33.8%) believed that India's clinical trial industry is ready to adopt digital twins, reflecting optimism among a third of the participants. In contrast, 16 respondents (11%) felt that the industry is not ready, showing a smaller but definite group with reservations. Overall,

the predominance of "Not sure" responses highlights the need for greater industry dialogue, awareness-building, and pilot projects to clarify the readiness and practicality of implementing digital twins in India. These results suggest that while there is cautious optimism, stakeholders still lack sufficient information or evidence to decisively conclude on India's preparedness.

4.3.6. Evaluate the potential of digital twins to mitigate specific delay factors

4.3.6.1 Potential of Digital twins in reducing clinical trial delays

Respondents were asked how likely they think digital twins are to reduce clinical trial delays in the future to evaluate perceived potential.

The findings indicate that the majority of participants hold a positive outlook on the potential of digital twins in reducing trial delays. Nearly half of respondents, 68 participants (46.9%), selected "Likely," while a further 19 participants (13.1%) selected "Very likely." Another 46 participants (31.7%) adopted a neutral stance, reflecting a substantial degree of uncertainty or cautious optimism. Only a small minority were sceptical, with 9 respondents (6.2%) selecting "Unlikely" and 3 respondents (2.1%) choosing "Very unlikely." The bar chart below outlines the responses.

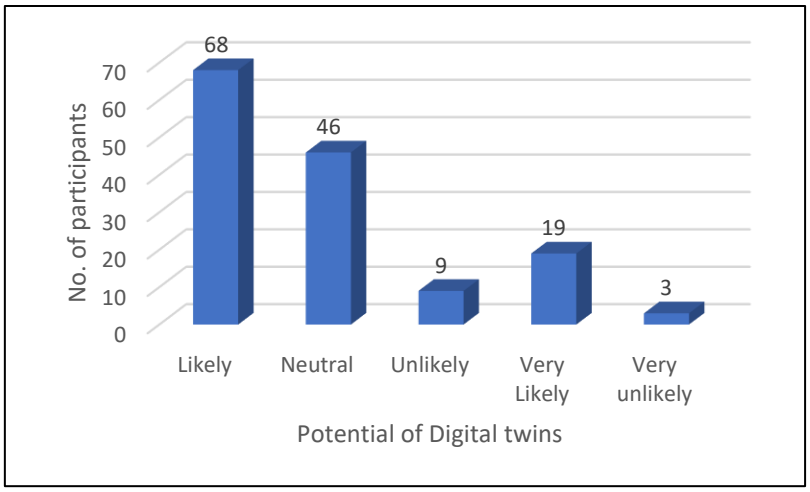

Fig. 29 Potential of Digital twins in reducing clinical trial delays

To test whether the distribution of responses occurred by chance or showed a significant pattern, a Chi-Square Goodness-of-Fit Test was applied. This test was chosen because the data are categorical and mutually exclusive (five likelihood categories) and the aim was to assess whether the observed frequencies significantly deviated from an expected uniform distribution (i.e., responses spread evenly across all options).

- Chi-square statistic (χ^2): 102.97
- Degrees of freedom (df): 4
- p-value: 2.3×10^{-21}

The test result is highly significant ($p < 0.001$), confirming that responses were not evenly distributed. Instead, there was a clear concentration of responses in the "Likely" and "Neutral" categories, with very few participants choosing the extreme ends of the scale.

4.3.6.2 Usefulness of Digital twins in clinical trial sector

This question aimed to identify the key domains within clinical research where digital twin technology is perceived to have the greatest potential impact, highlighting the specific areas where stakeholders believe its adoption could provide the most value.

The question was answered by 145 respondents, with multiple selections allowed, resulting in 435 total responses. The most cited area was patient selection and recruitment (78 respondents, 18%), followed by monitoring trial data in real time (73 respondents, 17%), and data modelling and simulations (69 respondents, 16%). Other key areas included trial protocol design (65 respondents, 15%), identifying early trends in protocol deviations (64, 15%), and predicting adverse events (63 respondents, 14%). A smaller group of 23 respondents (5%) were unsure about potential applications. These findings highlight strong recognition of digital twins in recruitment, monitoring, and predictive modelling within clinical trials. The responses are summarized in the chart beneath.

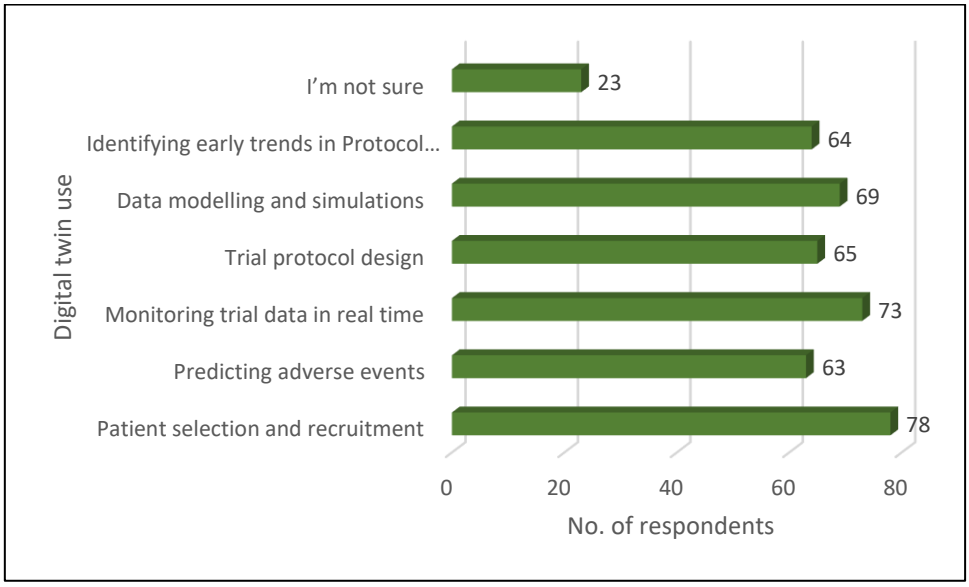

Fig. 30 Usefulness of Digital twins in clinical trial sector

4.3.6.3 Benefits in using digital twins in clinical trials

To further understand perceptions, respondents were asked: "What benefits do you see in using digital twins in clinical trials?". This open-ended question aimed to capture individual insights, highlighting perceived advantages beyond structured survey options.

Fig. 31 Benefits in using digital twins in clinical trials

The open-ended responses highlighted that digital twins in clinical trials are seen as most beneficial for reducing timelines and delays, improving patient recruitment, enhancing trial efficiency, and lowering costs. Respondents also noted advantages in trial design, management, regulatory approval, and patient safety, indicating a strong belief that digital twins can streamline processes while making trials safer and more reliable. The gist of responses are demonstrated in the image above.

4.3.7. Opinion on strategic implementation framework (recommendations for adoption in India)

4.3.7.1 Challenges in implementing digital twins in Clinical trials in India

To understand the barriers to innovation, respondents were asked what they perceive as the biggest challenges to implementing digital twins in clinical trials in India.

Based on the responses (n=473 selections across 7 categories), the analysis highlights the main challenges to implementing digital twins in India's clinical trials. The most cited barrier was lack of awareness (103 respondents, 21.8%), indicating that many stakeholders are still unfamiliar with the concept or its practical application. This was followed by the technical expertise gap (83 respondents, 17.6%), suggesting a shortage of skilled professionals capable of handling advanced digital technologies. Regulatory uncertainty (70 respondents, 14.8%) and high cost (66 respondents, 14%) were also significant concerns, reflecting hesitancy due to unclear compliance frameworks and financial feasibility. Other notable barriers included data privacy/security concerns (58 respondents, 12.3%), resistance to change (52 respondents, 11%), and limited digital infrastructure (41 respondents, 8.7%). The responses are summarized in the funnel chart beneath.

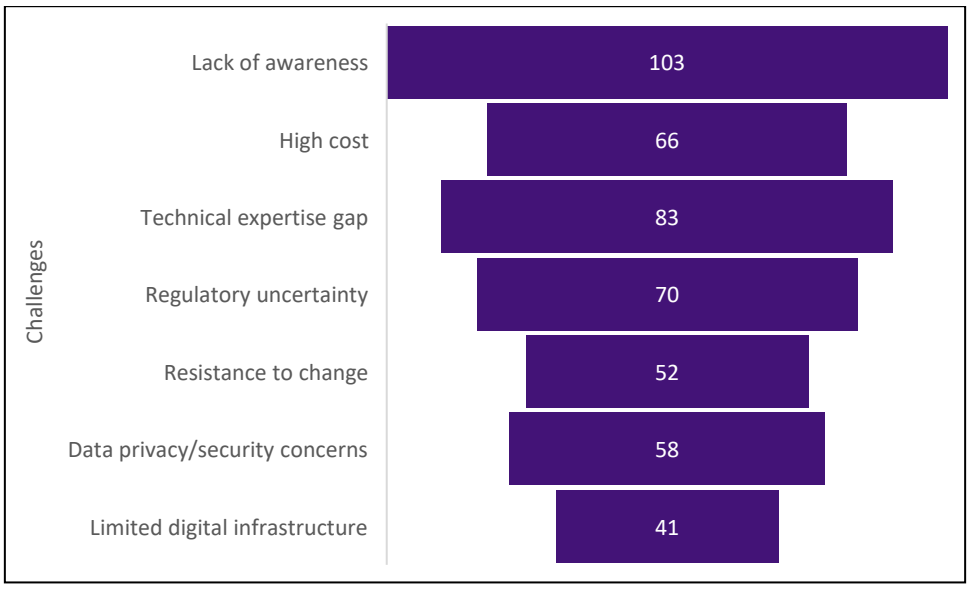

Fig. 32 Challenges in implementing digital twins in clinical trials

In summary, the results show that while the potential of digital twins is acknowledged, widespread adoption in India is constrained by awareness gaps, resource limitations, and regulatory hurdles. These insights highlight the need for targeted awareness programmes, investment in training, and clear policy guidelines to overcome the barriers.

4.3.7.2 Strategies to successfully adopt digital twin technology

To understand the enablers for successful adoption, the survey asked participants: *"What kind of support would be needed to successfully adopt digital twin technology in clinical trials?"* This question was designed to capture the resources, infrastructure, and policy-level interventions that stakeholders believe are essential for integrating digital twin solutions into India's clinical research landscape. The following chart shows the breakdown of responses.

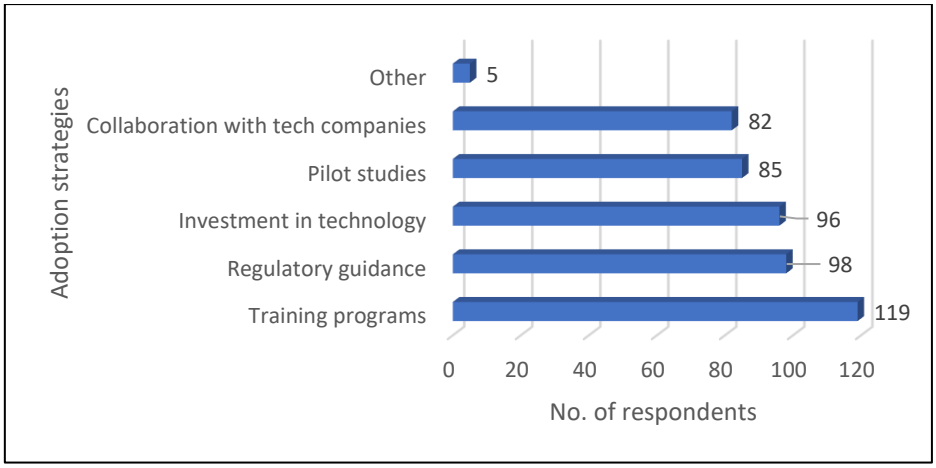

Fig. 33 Strategies to successfully adopt digital twin technology

Based on the responses, a total of 485 selections were made across different support categories, highlighting the multifaceted requirements for adopting digital twin technology in clinical trials. The most cited need was training programs, chosen by 119 respondents (24.5%), emphasising the importance of building technical knowledge and skills among clinical research professionals. Regulatory guidance was identified by 98 respondents (20.2%), reflecting the necessity for clear frameworks and compliance pathways. Similarly, investment in technology (96 responses, 19.8%) and pilot studies (85 responses, 17.5%) were seen as crucial steps to test feasibility and build confidence in adoption. Collaboration with technology companies was supported by 82 respondents (16.9%), underlining the value of partnerships between healthcare and tech sectors. A smaller proportion (5 responses, 1%) suggested other types of support, pointing towards more specific or individualised needs.

Overall, the findings indicate that while regulatory and financial support are important, human capacity building through training is considered the cornerstone for successful digital twin integration in India's clinical trial ecosystem.

4.3.7.3 Perception towards the use of digital twins in future clinical trials

The final question assessed the overall outlook of respondents on the potential role of digital twins in shaping the future of clinical trials, aiming to capture their level of optimism and confidence regarding its adoption and impact.

The responses to the final question, *"Overall, how positive are you about the use of digital twins in future clinical trials?"* highlight a generally optimistic outlook among participants. Out of a total of 145 respondents, the largest group, 52 participants (35.9%), reported being *positive*, while another 22 participants (15.2%) described themselves as *very positive*. Meanwhile, 43 respondents (29.7%) selected *neutral*, showing cautiousness or a wait-and-see approach. On the less favourable side, 26 participants (17.9%) were *slightly positive*, and only

2 respondents (1.4%) indicated they were *not positive*. The bar chart below depicts the responses.

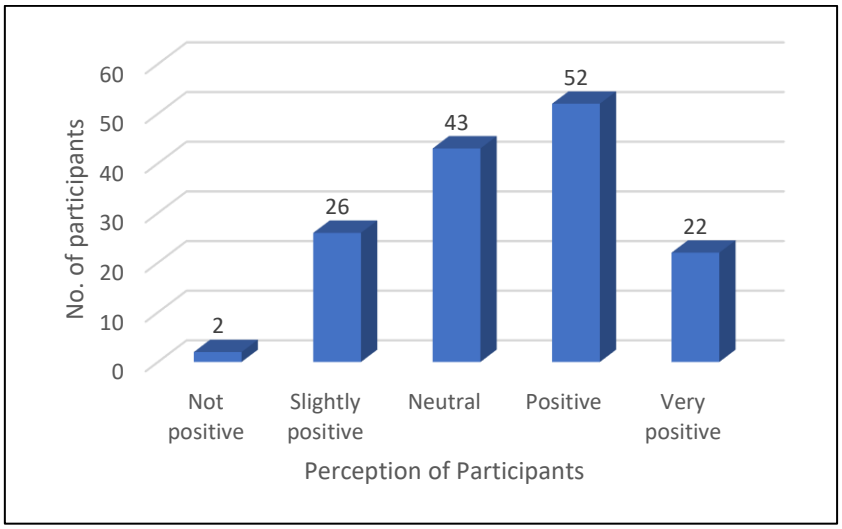

Fig. 34 Perception towards the use of digital twins in future clinical trials

Overall, the data demonstrates that more than half of the respondents lean towards a positive or very positive stance, suggesting strong openness to the adoption of digital twins in clinical trials. The relatively high proportion of neutral responses indicates that while optimism exists, there is still some uncertainty, possibly due to challenges such as awareness, cost, or regulatory clarity. This distribution reflects a generally positive sentiment, with room for further education and evidence-building to strengthen confidence in digital twin adoption.

4.4 Summary of Qualitative and Quantitative data analysis

The qualitative data analysis provided valuable insights into the underlying causes of clinical trial delays in India and the potential role of digital twin technology in mitigating these challenges. Across participants, regulatory bottlenecks, ethics committee backlogs, site-level inefficiencies, and patient recruitment difficulties emerged as the most significant barriers, echoing findings from existing literature. These systemic and operational issues highlight how India, despite its large patient pool and growing clinical research industry, continues to struggle with alignment to global timelines and standards. At the same time, interviewees emphasised practical solutions such as regulatory streamlining, digitalisation of documentation and approvals, improved site training, and enhanced patient engagement strategies, indicating that stakeholders are aware of feasible reforms.

Beyond identifying current inefficiencies, the analysis also highlighted cautious optimism regarding the adoption of digital twin technology. While awareness of the concept varied, participants recognised its potential benefits in trial simulation, protocol optimisation, recruitment forecasting, and adverse event prediction. These insights reinforce the argument that digital twins could transform trial efficiency by reducing delays, costs, and risks, aligning closely with the study's objectives. However, participants also underscored barriers to adoption, including high costs, lack of awareness and training, infrastructure gaps, and regulatory uncertainty, suggesting that readiness in the short term is limited. Importantly, the findings revealed a consensus that with global sponsors leading adoption and regulatory

frameworks evolving, India could gradually transition towards embracing such advanced technologies, positioning itself as a stronger player in digital clinical trials over the next decade.

Taken together, the qualitative analysis underscores both the entrenched challenges and future opportunities within India's clinical research ecosystem. The convergence of participant perspectives with existing scholarship strengthens the validity of the findings, while the divergence in views—particularly on readiness for adoption—highlights areas where further policy intervention and industry collaboration are required. Ultimately, the results point to a dual need: addressing long-standing operational bottlenecks through immediate reforms, while simultaneously building an enabling ecosystem for the gradual adoption of innovative solutions like digital twins.

The quantitative data analysis reveals clear trends in how clinical trial delays and digital twin technology are perceived within the Indian clinical research landscape. The results highlight that delays are seen as a widespread and persistent issue, particularly around regulatory processes and patient recruitment. These challenges are not evenly spread but rather concentrated in a few critical areas, indicating systemic inefficiencies that continue to hinder progress. Statistical testing further confirmed that participants held strong, directional views on the seriousness of delays and the potential of digital twins, reflecting a shared recognition of both the challenges and opportunities in the sector.

When examining perceptions of digital twin technology, the analysis shows that while awareness is gradually growing, familiarity remains relatively limited. Many respondents acknowledged uncertainty about the industry's readiness to adopt such innovations, which points to gaps in training, regulatory clarity, and technological infrastructure. Despite these reservations, there is an underlying sense of optimism, with a majority expressing positive expectations about the future role of digital twins in clinical research. This suggests that with the right support, such as targeted training programmes, clearer regulatory guidance, and collaborative initiatives, digital twins could play a transformative role in addressing delays and inefficiencies.

Overall, the quantitative findings emphasise the dual reality of the clinical trial ecosystem in India: entrenched structural challenges on the one hand, and emerging digital opportunities on the other. This tension reflects an industry in transition, where innovation holds considerable promise but requires significant groundwork in terms of policy, capacity building, and stakeholder engagement before it can be fully realised.

Chapter 5
Conclusions and Recommendations

CONCLUSION AND RECOMMENDATION

5.1 Overview

This chapter brings together the key findings of the study and addresses the research hypotheses outlined at the beginning of the project. By synthesising evidence from both the qualitative interviews and quantitative survey, the chapter evaluates whether digital twin technology can reduce delays in clinical trials in India and examines the perceptions, challenges, and readiness of professionals in this field. The conclusions are structured around the main and supporting hypotheses, providing a clear assessment of how far the research objectives have been achieved. In addition, this chapter outlines practical recommendations for industry stakeholders, regulators, and policymakers, offering strategies to address current barriers and enable the adoption of digital twins in clinical trial processes. Together, the conclusions and recommendations highlight the dual reality of India's clinical research ecosystem—one characterised by persistent structural challenges but also by significant opportunities for innovation and digital transformation.

5.2 Answering the hypotheses

5.2.1 Main Hypothesis: Digital twin technology can significantly reduce delays in clinical trials in India by improving planning, monitoring, and decision-making processes.

The findings of this research strongly support the main hypothesis. Both qualitative interviews and quantitative survey data demonstrated that digital twin technology has the potential to address the most persistent sources of delay in clinical trials in India. Regulatory bottlenecks, site readiness issues, and patient recruitment challenges were consistently identified as the primary causes of trial delays. Once participants were introduced to the concept of digital twins, they recognised that simulation and modelling capabilities could help overcome these barriers by streamlining trial planning, predicting recruitment bottlenecks, and enabling early identification of risks. For example, interviewees highlighted that trial protocols could be optimised across diverse populations before initiation, while survey participants viewed patient recruitment, monitoring, and predictive modelling as the most valuable applications of digital twins.

Quantitative evidence further reinforced this conclusion. Almost 60% of survey respondents stated that they believed digital twins are "likely" or "very likely" to reduce trial delays, with a highly significant chi-square result ($p < 0.001$) confirming that this pattern was not due to chance. In addition, open-ended survey responses emphasised that digital twins could shorten timelines, improve patient safety, reduce costs, and enhance data quality. These views align closely with the study's objectives of evaluating how emerging digital tools could directly mitigate delay factors such as patient recruitment inefficiencies, protocol amendments, and data monitoring delays.

However, while the potential of digital twins is clear, readiness for adoption remains limited. Awareness and familiarity among professionals are still emerging, with over two-thirds of respondents indicating that they were either not at all familiar or only slightly familiar with the concept. Interviews also revealed concerns about infrastructure gaps, regulatory uncertainty,

and the need for training, all of which temper immediate adoption prospects. Despite these constraints, the overall sentiment was one of cautious optimism, with professionals expecting that global sponsors and evolving regulatory frameworks would drive future adoption in India.

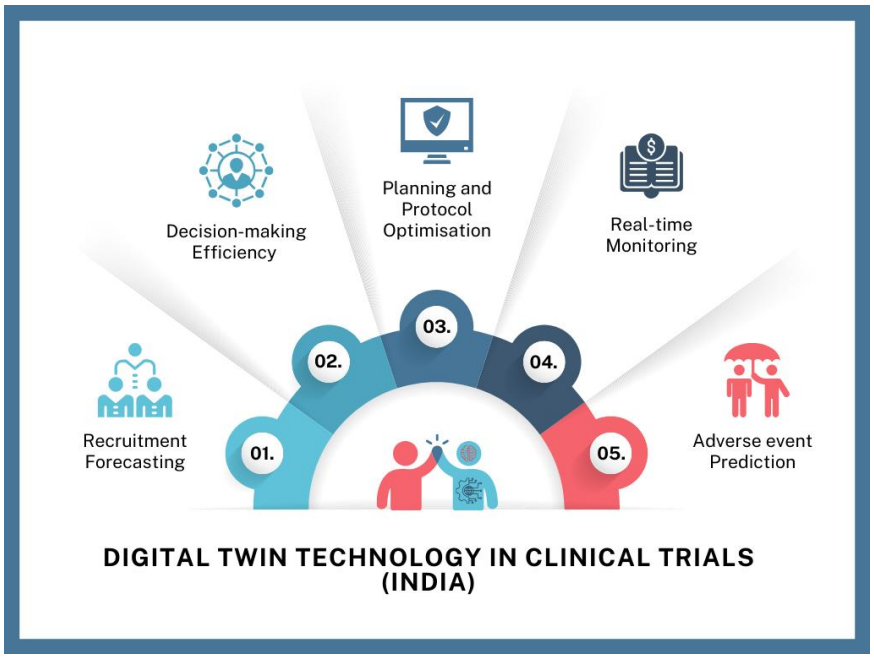

Fig. 35 Main Hypothesis Conclusion: Potential Role of Digital Twins in Reducing Clinical Trial Delays in India (source: developed by author using a Canva template, 2025)

5.2.2 H1: Clinical research professionals in India have limited awareness and understanding of digital twin technology.

This hypothesis is confirmed. Survey data revealed that only about half of respondents (51%) had heard of the term "digital twin" prior to the study, and a significant proportion reported being "not at all" or "slightly" familiar (67%). Interviews further highlighted this gap, with some participants encountering the concept for the first time during the discussion. Limited awareness was also identified as the most cited barrier to adoption (21.8% of survey responses). These results demonstrate that while curiosity exists, professional familiarity with digital twins remains limited in the Indian context, underlining the need for education and training initiatives.

5.2.3 H2: The adoption of digital twin technology in clinical trials is perceived to improve trial efficiency and reduce time to completion.

The hypothesis is strongly supported. Both data strands highlight optimism regarding the efficiency benefits of digital twins. Survey respondents most frequently associated the technology with improvements in patient recruitment, real-time monitoring, and predictive modelling. Open-ended responses emphasised reduced timelines and better efficiency as key benefits. Interviewees similarly pointed out that digital twins could accelerate protocol finalisation, predict recruitment bottlenecks, and enhance safety oversight. Overall,

professionals perceived digital twins as a practical tool to streamline processes, shorten timelines, and improve trial quality.

5.2.4 H3: Key challenges to adopting digital twins in clinical trials include lack of infrastructure, training, and regulatory clarity.

This hypothesis is validated by the findings. Survey participants identified lack of awareness, expertise gaps, regulatory uncertainty, and high costs as the leading barriers. Similarly, interviewees repeatedly cited inadequate training, infrastructure limitations in rural sites, resistance to change, and unclear regulatory pathways as major challenges. Concerns over data privacy and integrity were also highlighted. Together, these responses confirm that without significant investments in infrastructure, workforce capacity building, and the development of clear DCGI/ICMR guidelines, large-scale adoption of digital twins in India will face major obstacles.

5.2.5 H4: There is a positive attitude among professionals towards integrating digital innovations like digital twins in future clinical trial strategies.

The evidence strongly supports this hypothesis. More than half of survey respondents described themselves as positive or very positive about digital twin adoption in future clinical trials, with only a small minority being sceptical. Interviews reflected cautious optimism, with many participants recognising that global sponsors and large CROs are likely to lead adoption, gradually influencing the Indian ecosystem. While short-term readiness was considered low, the long-term outlook was perceived as favourable, contingent on regulatory alignment and training support.

5.3 Study Implications

This study carries several important implications for research, practice, and policy, particularly within the context of clinical trials in India and the adoption of digital twin technology.

5.3.1. Theoretical Implications

The findings contribute to the growing body of knowledge on digital health innovations by contextualising digital twin technology within clinical trial management. While much of the existing literature has focused on global perspectives, this study highlights region-specific challenges in India, such as regulatory bottlenecks, patient recruitment difficulties, and site-level inefficiencies. By linking these barriers with the potential applications of digital twins—such as simulation of trial protocols, predictive modelling, and personalised pathways—the study extends existing theory to a new and underexplored context. This supports future academic work by framing digital twins not just as a technical innovation but as a socio-technical solution shaped by local infrastructure, regulations, and stakeholder readiness.

5.3.2. Practical Implications

For clinical research professionals and pharmaceutical companies, the study provides actionable insights into how digital twins could address major trial delays. Specifically, the findings suggest that digital twins can help improve patient recruitment and retention by predicting suitable participant profiles, reduce regulatory and operational delays by simulating trial protocols, and enhance monitoring through real-time predictive analytics. These insights can guide organisations in prioritising investments in digital health technologies and in training

staff to work with new tools. Furthermore, recognising barriers such as high costs, lack of awareness, and limited infrastructure prepares organisations to plan phased adoption strategies rather than rushing into full-scale implementation.

5.3.3. Policy Implications

At a policy level, the research underscores the urgent need for regulatory evolution in India. Current processes, such as lengthy approvals from the DCGI and ethics committees, were consistently highlighted as barriers to efficiency. Policymakers could draw on these findings to introduce regulatory sandboxes or pilot frameworks that allow for controlled experimentation with digital twins. This would not only accelerate adoption but also ensure ethical safeguards and patient protection are maintained. The study also points to the importance of cross-sector collaboration between regulators, industry leaders, and academic institutions to build awareness and set guidelines for digital twin use in clinical trials.

5.4 Study Limitations

Like any research, this study has certain limitations that should be acknowledged. Firstly, the survey responses and interviews relied on self-reported data from clinical research professionals, which may be subject to personal biases or selective recall. While efforts were made to include diverse perspectives, the sample size—particularly for interviews—was limited, as more than 25 professionals were contacted but only 8 agreed to participate. This restricted the diversity of viewpoints and may not fully represent the views of all stakeholders in India's clinical trial ecosystem.

Secondly, the study explored digital twin technology in a largely conceptual context, as its practical implementation in India is still at an early stage. This means the insights gathered are more reflective of perceptions, expectations, and readiness rather than direct empirical evidence of outcomes. The short research timeline of 12 weeks also posed constraints, making it necessary to focus the survey on a particular region—specifically the northwestern part of India—rather than capturing perspectives across the country. This regional concentration may limit the broader relevance of findings to the broader national context.

Additionally, the rapid pace of technological change in the biopharmaceutical industry presents another limitation, as some practices or challenges highlighted in this research may evolve quickly, affecting the long-term relevance of the findings. Furthermore, certain key perspectives, such as those of patients and regulators, could not be directly included due to time and access challenges, which might have added further depth and balance to the study.

Despite these limitations, the study provides a valuable foundation for future research. It highlights the current challenges and opportunities in India's clinical trial landscape, while offering initial insights into the potential role of digital twins. Future studies can build on this work by expanding the participant base, including more diverse stakeholders, and assessing real-world pilot projects of digital twins in clinical trials.

5.5 Recommendations for Future Research

While this study has provided valuable insights into the role of digital twin technology in addressing clinical trial delays in India, it also highlights several areas that warrant further exploration.

5.5.1 Empirical Testing of Digital Twin Applications

This study relied on professional perceptions and existing literature to evaluate the potential of digital twins. Future research should focus on pilot projects or case studies that empirically test digital twin models within ongoing or upcoming clinical trials. Measuring their impact on trial timelines, costs, and patient recruitment outcomes would provide stronger evidence of their practical value.

5.5.2 Broader Geographic Comparisons

Although this research was situated in India, clinical trials are global in nature. Comparative studies between India and other countries—both emerging and established clinical research hubs—could provide a richer understanding of how infrastructure, regulations, and stakeholder readiness influence digital twin adoption. Such research would help identify best practices and scalable strategies.

5.5.3 Patient-Centric Perspectives

The current study focused mainly on industry professionals and clinical researchers. Future studies should also explore patient perceptions of digital twin technology. Understanding patients' willingness to participate in digitally enhanced trials, their concerns around data privacy, and their trust in such innovations would add an important dimension to the literature.

5.5.4 Regulatory and Ethical Frameworks

Further research is needed to examine how regulatory bodies in India can create supportive frameworks for adopting digital twins. Studies that assess regulatory sandbox models, data governance mechanisms, and ethical implications will be crucial in ensuring safe and compliant implementation of these technologies.

5.5.5 Long-Term Organisational Readiness and Costs

Since cost and infrastructure were identified as key barriers, future research could focus on developing cost–benefit models for adopting digital twins. Additionally, examining organisational readiness, including workforce training needs and cultural acceptance of digital tools, would provide valuable guidance for both industry and policymakers.

5.6 Conclusion and Reflections

The findings of this study demonstrate that digital twin technology has significant potential to reduce delays in clinical trials in India by strengthening planning, forecasting, monitoring, and decision-making processes. Both quantitative and qualitative results confirmed that regulatory bottlenecks, patient recruitment difficulties, and site inefficiencies are the most pressing delay factors, and digital twins offer practical solutions through protocol optimisation, recruitment prediction, and real-time oversight. Although current awareness and familiarity among professionals remain limited, the overall outlook towards adoption is positive, with a majority recognising the long-term value of digital twins in improving trial efficiency and reliability.

At the same time, the study highlights that adoption will not be straightforward. Major challenges, including a lack of training, infrastructure gaps, regulatory ambiguity, and high implementation costs, were consistently identified as barriers. These findings indicate that digital twin technology is not an immediate remedy but rather a medium- to long-term innovation requiring systemic reforms. Regulatory clarity, investment in digital infrastructure, workforce training, and collaborative pilot projects are essential to enable successful adoption. With global sponsors and contract research organisations likely to lead initial implementation, India's pathway towards integration is expected to be gradual but ultimately transformative.

Reflecting on the wider implications, this research underscores that digital innovations cannot succeed in isolation; they must be embedded within a supportive ecosystem of policy, capacity building, and stakeholder collaboration. The study reveals a dual reality in India's clinical trial environment: persistent inefficiencies continue to undermine competitiveness, yet there is also growing openness to digitalisation and technological change. This suggests that India is at a critical juncture where addressing systemic challenges while embracing innovation could allow it to strengthen its role in global clinical research. By gradually adopting digital twin technology, supported by regulatory, infrastructural, and professional readiness, India has the potential to transform clinical trial timelines, improve patient outcomes, and establish itself as a leader in digital-enabled research.

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APPENDIX

APPENDICES

Appendix A: Ethics form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India

RESEARCHER'S NAME: Abna Sreedhar Vysiapat

PROGRAMME OF STUDY: MSc. Pharmaceutical Business and Technology

SUPERVISOR'S NAME: Francesca Rizzarello

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: 

DATE: 01.07.2025

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☒

SUPERVISOR SIGNATURE: Francesca Rizzarello 

DATE: 01/07/2025

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

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

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

Despite the promise of new digital innovations, the pace of transformation in clinical trials has been slower than expected, especially when compared to progress seen in other industries. This research will investigate the barriers to implementation and explore strategies to accelerate the adoption of data-driven technologies in clinical trial settings. A significant number of clinical trials fail due to challenges in recruitment and participant enrolment, with nearly 86% of trials not meeting their enrolment targets and approximately 32% of Phase III trials failing specifically due to recruitment-related issues. One major contributing factor is the underrepresentation of hard-to-reach populations, such as racial and ethnic minorities, which can compromise the quality of the study and reduce the generalizability of its findings. Digital twins could improve clinical trials by adding simulation, monitoring, and efficiency. India shows promise with its growing digital health systems, but faces data, technical, and regulatory barriers. This study is ideally placed to fill the major gap in Indian-focused research—providing practical insights for medicine developers, regulators, and healthcare innovators.

Objectives:

- To identify and categorize the primary causes of clinical trial delays in India through a literature review
- To analyze the current adoption status of digital twin technology in the clinical research sectors of India
- To evaluate the potential of digital twins to mitigate specific delay factors (e.g., patient recruitment, trial protocol adjustments, regulatory approvals)
- To propose a strategic implementation framework that outlines 3–5 practical recommendations for leveraging digital twins to reduce trial delays in India

1.2 Research methodology:

Research Philosophy: The philosophical approach for this research is pragmatism. Pragmatism is suitable because it focuses on finding practical solutions to real-world problems by using a mix of methods that best help to answer the research question.

Research Approach – Deductive and Inductive: The research uses a combined deductive and inductive approach.

Methodological Choice – Mixed Methods: The study follows a mixed-methods methodology, which includes both quantitative and qualitative data collection. Quantitative data will be gathered through surveys whereas qualitative data will come from semi-structured interviews with selected professionals.

Research Strategy – Surveys and Interviews: Quantitative data: Collected through online surveys, targeting professionals working in clinical research, pharma companies, or regulatory bodies in India. These will help to identify common causes of delays, awareness levels of digital twins, and openness to digital innovations.

- Qualitative data: Collected through semi-structured interviews with selected experts such as Clinical Research Associates, CRO representatives, and digital health technology consultants. Interviews will provide deeper insights into the challenges and opportunities around using digital twins in Indian clinical trials.

Time Horizon – Cross-sectional: The research will use a cross-sectional time horizon, meaning that all data will be collected at a single point in time, over a 3-weeks period.
Techniques and Procedures – Data Collection and Analysis: For data collection, surveys will be created using Google Forms and shared with clinical research professionals via email and LinkedIn. Participants will be selected using purposive sampling, focusing on those with at least two years of experience in clinical trials or digital health in India.

SECTION 2: POSSIBLE ETHICAL ISSUES

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

SUBJECT MATTER

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

RESEARCH PROCEDURES

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

PARTICIPANTS

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

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

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

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

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

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

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

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study
For this study, participants will include professionals who work in clinical trials such as Clinical Research Associates (CRAs), Clinical Trial Managers, Project Managers, Directors, and/or Regulatory Affairs experts. These individuals have more than 2 years of experience in the pharmaceutical and clinical research industry, especially in India. They have been chosen because they understand the common reasons behind clinical trial delays and can give informed opinions on whether digital twin technology can help. Their insights will help the research gather both expert views (through interviews) and broader opinions (through surveys) to explore the topic in a meaningful way.

4.2 How do you plan to gain access to/contact/approach your participant(s).
I plan to contact participants through previous professional connections and referrals from common friends. I will also approach them directly via their LinkedIn profiles, based on their relevant experience.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

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

Please confirm below that your information letter covers:

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

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

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

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

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

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

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

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

The research data will be safely stored on my personal computer in a password-protected and encrypted folder. I will follow all ethical guidelines and GDPR rules to ensure the privacy and security of participants' information.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

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

No

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

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

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

SECTION 9: DOCUMENT CHECKLIST

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

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

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

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

For Student:

STUDENT SIGNATURE: 

DATE: 01.07.2025

Appendix B: Participant Information Leaflet

Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India

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

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Abna Sreedhar Vysiapat, and I am a Masters student studying Pharmaceutical Business and Technology at Griffith College Dublin, Ireland. I am doing this study to explore how digital twin technology (virtual replica of systems or processes) could help reduce delays in clinical trials in India. This research is part of my final project for my MSc degree. The study aims to gather opinions and experiences from professionals working in the clinical trial and pharmaceutical field. I am not expecting any specific outcome and want to understand different viewpoints fairly and openly.

WHAT WOULD TAKING PART INVOLVE?

If you agree to take part in this study, you will be asked to take part in a one-on-one interview. The interview will last around 25-30 minutes and can be done online at a time that suits you. With your permission, the interview will be audio/video-recorded so I can accurately transcribe and analyse your responses later. All information you share will be kept private and only used for this research. There are no known risks or direct impacts to you or your daily life/ work life from taking part in this research.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in this research because of your professional experience in the pharmaceutical or clinical research field. Your knowledge and insights into clinical trial processes, especially in the Indian context, are valuable for understanding the challenges and possible benefits of using digital twin technology. I identified you through professional networks and recommendations, as someone who can provide meaningful input for this study.

DO YOU HAVE TO TAKE PART?

Please note that your participation in this study is entirely voluntary. You have the full right to decide whether or not to take part, and choosing not to participate will have no negative consequences for you. During the study, you can refuse to answer any question or withdraw from the research at any time without giving a reason. If you decide to withdraw, please contact me at my email abnasreedhar.vysiapat@student.griffith.ie

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

This research may help improve understanding of how digital twin technology could reduce delays in clinical trials, which could benefit the pharmaceutical industry in the future. While there are no physical risks involved, there is a small chance of discomfort if you are asked to reflect on challenges or frustrations related to your professional work. To reduce this risk, you are free to skip any questions you do not wish to answer. Your personal information will be kept strictly confidential, and all data will be stored securely following GDPR guidelines. If you feel any stress or discomfort during or after the interview, you can stop at any time and are encouraged to contact me for support or guidance.

WILL TAKING PART BE CONFIDENTIAL?

All information you provide in this study will be treated with strict confidentiality and your identity will remain anonymous in the final report. Your name or any identifying details will not be included in the findings. If any confidential company information is shared during the interview, it will only be used with prior permission, and no company names will be mentioned without approval. Signed consent forms and audio recordings will be collected and securely stored but will not be shared with anyone else. These recordings will only be used to transcribe the data accurately and will be deleted after the study is complete.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All research data will be stored securely on my personal computer in a password-protected and encrypted folder. Only I, as the researcher, will have access to this data. Any signed consent forms and audio recordings will also be stored safely and separately from the analysis data to protect participant identity. The data will be kept for a period of two years after the completion of the study, in line with academic and ethical guidelines. After this period, all data—including audio recordings and personal information—will be permanently deleted to ensure full confidentiality and compliance with GDPR regulations.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The final research project will be submitted as part of the requirements for my MSc in Pharmaceutical Business and Technology. At present, there are no plans for conference presentations or publication beyond this academic purpose. However, it is important to note that all student dissertations are stored in the college library and may be made accessible to other students, staff, and researchers. In some cases, they may also be included in online

academic repositories or e-journals if deemed suitable by the college. All identifying participant information will be removed to ensure confidentiality in any shared versions.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Researcher details

Name – Abna Sreedhar Vysiapat- student, MSc. Pharmaceutical Business & Technology, Griffith College Dublin, Ireland

Contact details- abnasreedhar.vysiapat@student.griffith.ie

[THANK YOU]

Appendix C: Participant Consent Form

Griffith College

Consent to take part in research

Bridging the Gap: How Digital Twins Can Address Clinical Trial Delays in India

The researcher retains one copy signed by both themselves and the participant. The participant should also receive a copy of consent form as a record of what they have signed up to.

- 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 one-on-one interview. The interview will last around 25-30 minutes and will be done online. It will be audio/video-recorded so it can accurately transcribed and analysed later
- 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.
- If conducting interviews by Skype/Zoom, I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in the dissertation of the researcher, at present and any possible future conference presentations, published papers, ejournals, library etc.
- 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 in researcher's personal laptop in password protected and encrypted folder and the researcher only will have the access to those files until two years after the date of researcher's exam boards
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for two years from the date of the researcher's exam board.
- 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- Abna Sreedhar Vysiapat

Degree Programme- MSc. Pharmaceutical Business & Technology

College Details- Griffith College Dublin, Ireland

Contact number- +353894585957

Contact mail- abnasreedhar.vysiapat@student.griffith.ie

Signature of participant

[Full Name – Printed]

Signature of research participant

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

Signature of researcher

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

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

Signature of researcher

Appendix D: Questions for Interview

1. Can you briefly describe your current role and experience in the pharmaceutical or clinical research industry?
2. What types of clinical trials have you worked on (e.g., phases, therapeutic areas)?
3. In your experience, what are the most common reasons for delays in clinical trials in India?
4. How do these delays affect the overall progress and outcomes of a clinical trial?
5. Have you heard about the use of digital twins in healthcare or clinical trials before? If yes, what do you understand by the term?
6. What are your initial thoughts or opinions on using digital twins in clinical trials?
7. How do you see digital twins helping in areas such as patient recruitment, protocol design, or data monitoring?
8. What challenges do you think pharmaceutical companies in India might face when adopting digital twin technology?
9. Do you think the clinical trial ecosystem in India is ready to adopt such digital solutions? Why or why not?
10. Based on your experience, do you believe digital twins have the potential to transform how clinical trials are conducted in India?
11. What recommendations would you give for successfully implementing this technology in future clinical trials?

Appendix E: Questions for Survey

Introduction

This study explores how digital twin technology can help reduce delays in clinical trials in India. It aims to understand the potential benefits, challenges, and views of professionals working in clinical research. The findings will help identify how digital innovations can improve trial efficiency and support faster drug development. The survey should take approximately 5–10 minutes to complete. Participation is completely voluntary, and all responses will be kept anonymous and confidential.

1. Understanding of the Research Purpose:
   "I have read the information provided and understand the purpose of this research study, which explores how digital twin technology may help reduce clinical trial delays in India."
   - Yes, I understand
   - No, I do not understand

2. Consent to Participate:
   "I voluntarily agree to take part in this research study. I understand that my responses will be kept confidential and that I can withdraw at any time without any consequences."
   - Yes, I give my consent
   - No, I do not give my consent

3. What is your current job title/role?
   - Clinical Research Associate
   - Clinical Trial Manager
   - Project Manager
   - Director
   - Regulatory Affairs Specialist
   - Other (please specify): _____

4. How many years of experience do you have in clinical research or the pharmaceutical industry?
   - Less than 1 year
   - 1–3 years
   - 3–7 years
   - 7–10 years
   - More than 10 years

5. What type of organization do you work with?
   - Pharmaceutical Company
   - Contract Research Organization (CRO)

- Hospitals
- Regulatory Body
- Other (please specify): _____

6. Have you worked directly on clinical trials in India?
   - Yes
   - No

7. In your experience, what are the top causes of delays in clinical trials in India? (Select all that apply)
   - Regulatory approvals
   - Patient recruitment
   - Protocol amendment
   - Ethics committee delays
   - Site readiness
   - Budget constraints
   - Data collection methods
   - Data monitoring methods
   - Clinical Trial Supplies
   - Other: _____

8. From your experience how serious clinical trial delays are in India?
   - Not serious
   - Slightly serious
   - Moderately serious
   - Very serious
   - Extremely serious

9. Have you heard of the term "Digital Twin" in a clinical trial context before this survey?
   - Yes
   - No
   - Not sure

10. How familiar are you with the concept of Digital Twins in clinical research?
    - Not at all familiar
    - Slightly familiar
    - Moderately familiar
    - Very familiar
    - Extremely familiar

11. Based on your knowledge, what do you believe a Digital Twin can do in a clinical trial? (optional open-ended)

12. How likely is it that digital twins can reduce clinical trial delays?
    - Very unlikely

- Unlikely
- Neutral
- Likely
- Very likely

13. In which areas could digital twins be most useful? (Select all that apply)
    - Patient selection and recruitment
    - Predicting adverse events
    - Monitoring trial data in real time
    - Trial protocol design
    - Data modelling and simulations
    - Identifying early trends in Protocol deviations
    - I'm not sure

14. What benefits do you see in using digital twins in clinical trials? (open-ended)

15. What do you think are the biggest challenges to implementing digital twins in India? (Select up to 3)
    - Lack of awareness
    - High cost
    - Technical expertise gap
    - Regulatory uncertainty
    - Resistance to change
    - Data privacy/security concerns
    - Limited digital infrastructure

16. Do you think India's clinical trial industry is ready to adopt digital twins?
    - Yes
    - No
    - Not sure

17. What kind of support would be needed to successfully adopt digital twin technology? (Select all that apply)
    - Training programs
    - Regulatory guidance
    - Investment in technology
    - Pilot studies
    - Collaboration with tech companies
    - Others: _____

18. Overall, how positive are you about the use of digital twins in future clinical trials?
    - Not positive
    - Slightly positive
    - Neutral
    - Positive
    - Very positive

19. Would you be willing to participate in a follow-up interview about this topic? If Yes, then please mention your email ID below
    - _____