BRIDGING THE DIGITAL DIVIDE: EMPOWERING CLINICAL TRIALS OFFICES FOR DECENTRALIZED CLINICAL TRIALS

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ABSTRACT

The traditional model of clinical trials, which is conducted in centralized locations, has been criticized for being costly, inefficient, and a hindrance to patient access. Decentralized clinical trials, in contrast, leverage digital platforms and technologies to bring clinical research closer to patients. Studies have reported that for pharmaceutical companies this has meant a reduction in lengthy trial timelines, faster development of drugs, and a potential reduction in financial burden. However, the successful execution of decentralized clinical trials hinges on empowering clinical trials offices. These offices face challenges in implementing digital technologies that are presently overlooked, leading to a lack of investment. Clinical trials offices require investment in training staff, integrating existing systems and working across various sponsors. This research explored the oversight of impact of digitalization on clinical trials offices through a structured survey. This method enabled the ability to understand the value of digitalization through the perspective of clinical trial offices. Results revealed that digital tool adoption led to a perceived reduction in staff turnover but a decrease in minority patient recruitment. The digital maturity of a clinical trials office revealed a perceived increase in data quality as there was more engaged in the implementation and execution of tools. Alternatively, study start-up timelines were perceived to have increased with digital tools being implemented bringing to light the complexity of the ecosystem's clinical trials offices and their operations. A qualitative analysis of an open response question provided insights from key stakeholders involved in clinical trial management revealing issues with one-size fit all models of digital tools, the lack of oversight and training of staff as well as the engagement of key stakeholders as tools get vetted. This dissertation provides insight into the effects of digitalization on key metrics for clinical trials offices while bringing to light how far behind we still are at truly understanding the impact of investing and implementing digital tools in clinical trials offices.

KEY WORDS: clinical trials, digitalization, digital maturity, decentralized clinical trials, digital tool adoption, digital technologies

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“Some beautiful paths on our journey can only be discovered when you dare to face the unknown.”

– Daniela Birch

During my master's program, a professor casually mentioned the idea of pursuing a doctoral degree. At the time, my first thought was, "That's pure insanity!" It certainly wasn't a planned stop on my life's journey. But as someone who firmly believes that God has bigger plans than one could ever imagine, I embarked on a journey that introduced me to people and experiences that He knew would guide me through the unknown like no other. For this, I am immensely grateful and forever changed

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INTRODUCTION

Clinical trials are commonly associated with pharmaceutical companies, which financially support investigational products, such as study drugs, in said trials. However, the pivotal role played by hospitals and clinical sites in providing patients and generating data for United States Food and Drug Administration (FDA) filings and eventual approvals is often overlooked (Advarra, 2021). These institutions are essential for the success of clinical trials, as they ensure that the trials are conducted ethically, and that the data collected is reliable. Without the involvement of hospitals and clinical sites, pharmaceutical companies would struggle to bring new drugs to market. Therefore, recognizing the contributions of these entities is vital for understanding the full landscape of clinical research.

Decentralized clinical trials (DCTs) gained prominence during the COVID-19 pandemic, expanding access to research through virtual visits, remote monitoring, and home-based assessments. The urgency imposed by the pandemic necessitated the decentralization of trials, which allowed for continued research despite lockdowns and social distancing measures. This shift not only made clinical trials more accessible to broader populations but also introduced new potential efficiencies to the clinical trials process. Patients could participate in trials from the comfort of their homes, reducing the burden of travel and making it easier to recruit and retain participants (Khozin & Coravos, 2019). As a result, DCTs have become a significant innovation in the field of clinical research.

While recent studies (DiMasi et al., 2023) have demonstrated the benefits of decentralization for pharmaceutical companies, a critical question arises regarding the impact of decentralized clinical trials on the return on investment (ROI) for clinical trials offices conducting clinical trials. Oncology trials typically involve hospitalizations, in-person activities like imaging and surgical procedures, and complex blood collection and tissue biopsy processes (Dorsey et al., 2020). Oncology drugs and infusions entail higher risks, often requiring medical oversight during study drug administration (Mackley et al., 2021). Implementing decentralized clinical trials necessitates investments by hospital systems in upgrading various systems, including clinical trial management systems, electronic regulatory binders, data collection platforms, and electronic medical records (Kayentis, n.d.). Often clinical trials offices are tasked with the oversight and integration of digital tools and technologies into the clinical trial processes, providing the training and support of staff, and monitoring quality, efficiency, and regulatory compliance.

Considering the investments made by clinical trial offices and in turn hospital sites to facilitate decentralized clinical trials, it becomes crucial to determine the value of their facilitation. Revenue generation can stem from both tangible and intangible elements, raising questions about the benefits decentralized clinical trials bring to cancer centers and the patients they serve (Reites, 2021b). This research explored the question, *How does digitalization, the foundation of decentralized clinical trials, impact the clinical trials offices that operationalize clinical trials at hospital/clinical sites?* in two parts, i.e., (Q1) *How does digital adoption impact the staff of clinical trials offices and patient accruals for the trials these offices support?* and (Q2) *How does the digital* *maturity of the clinical trials offices that adopt digital tools impact the quality of the data and the study start-up process of clinical trials?*

This dissertation is structured as follows: First, we provide an overview of the history of clinical trials, decentralized clinical trials, the impact of COVID-19 on trial operations, the FDA's evolving stance on decentralized clinical trials in clinical research, and gaps in existing research for investigational sites. Chapters two and three explore the theoretical foundation of the proposed research and outline the methods employed to investigate the hypotheses generated from the research question. The dissertation concludes by discussing the expected contribution, to spark interest and generate insights that can inform cancer center leadership and inspire further discussion in the future. The goal of this research ultimately was to investigate the benefits of incorporating digitalization to accommodate decentralized clinical trials for cancer centers, comparing the investment made and the return that the investment yields for both tangible and intangible measures of clinical trial success that revolve around the patients that drive the cost of clinical trials at investigational sites.

Brief History of Clinical Trials

According to the National Institute of Health (NIH), a clinical trial is a research study in which human subjects are prospectively assigned to one or more interventions (including placebos or control groups) to evaluate their effects on health-related biomedical or behavioral outcomes (NIH Grants & Funding, n.d.). Clinical trials are conducted to determine the safety and efficacy of new medical treatments, such as devices, biologics, drugs, and procedures. Drug development requires clinical trials to ensure the best options of care for patients, which is an essential part of the drug development process (U.S. Food & Drug Administration, n.d.).

The history of clinical trials dates back to ancient civilizations when people began to experiment with different treatments, i.e., herbs, drugs, and unconventional therapies to investigate what worked and what did not. With the initial roots in observational medicine, there was a religious undertone to the interventions and rooted in the concept of trial-and-error testing over time (Junod, 2008). The ancient Egyptians used leeches to bleed patients, and the ancient Greeks used willow bark to treat pain (Cavaillon, 2021). However, it was not until the 18th century that the first clinical trial was conducted more systematically (Collier, 2009).

In 1537, Ambroise Paré, a French military surgeon, is credited for the first clinical trials. An unintentional trial, when faced with no boiling oil which was the standard treatment for battle wounds, resorted to utilizing a mixture of egg yolk, rose oil, and turpentine. When comparing soldiers who had received the mixture to those who had received the conventional treatment of the boiling oil, Paré found that there was less swelling, irritation, and pain (Markatos et al., 2018).

In 1747, British naval surgeon James Lind conducted what is often considered the first planned clinical trial, targeting treatments for scurvy. At the time of Lind's trial, scurvy was a leading cause of death among sailors: Caused by the deficiency of Vitamin C, scurvy is characterized by bleeding gums, weakness, and the opening of healed wounds. For Lind's trial, he placed twelve sailors with scurvy into six groups and provided each group with a different treatment modality. The treatments included oranges and lemons, cider, vinegar, seawater, an elixir of vitriol, and nutmeg-sized paste (consisting of garlic, horse radish, balsam of Peru, mustard seed, and gum). These treatments were taken in a controlled setting, i.e., the sailors were placed in the same areas and maintained the same diets. The results of Lind's trial revealed that the sailors who received oranges and lemons recovered quicker than the sailors who received the other treatments. This trial helped to establish the importance of vitamin C in preventing and treating scurvy. This also gave way to the first controlled clinical trial in which biases were controlled while conducting the trial (White, 2016).

In 1863, Austin Flint, a U.S. physician, introduced the first trial to incorporate the comparison of a placebo, i.e., inactive or "dummy" treatment, versus an active treatment (Bhatt, 2010). In his study, he studies the effects of an herbal extract shown to not affect rheumatic fever to the standard treatment regimen. Conducted on thirteen patients, the study showed that those receiving the herbal extract reported feeling relief showed improvement in the symptoms and developed the concept of the placebo effect (McEwen, 2022).

In the 20th century, there were several important advances in the world of clinical trials. One large contributor to their widespread adoption was the establishment of the Federal Food, Drug, and Cosmetic Act in 1938, hastened by what would become known as the largest mass poisoning of the 20th century. Used to fight streptococcal infections and considered a wonder drug of its time, sulfanilamide was widely used in tablet form. In 1937, a salesman for S.E. Massengill Co reported a rise in demand in the southern states of the United States for an elixir form. Based on this feedback, Harold Cole Watkins, the chief pharmacist for the company, developed an elixir of sulfanilamide in diethylene glycol, i.e., antifreeze, which is deadly upon consumption. S.E. Massengill

Co’s control lab never tested the agent for toxicity and found the elixir sulfanilamide satisfactory for flavor, appearance, and fragrance. Six hundred and thirty-three shipments of the Elixir Sulfanilamide were shipped out across the country in early September of 1937. By October 1937, physicians were reporting deaths of patients, mostly children, being treated for sore throat with the elixir to was eventually reported to the Food and Drug Administration (FDA). Diethylene glycol was found to be a toxic agent and most of the distributed elixir was pulled from the market (Ballentine, 1981). The sulfanilamide poisonings gave way to the hastened establishment of the Federal Food, Drug, and Cosmetic Act which was first introduced to the Senate in 1933 and stalled until 1938 when it was signed by Congress (Zoon & Yetter, 2007).

The 1938 Food, Drug, and Cosmetic Act required drug manufacturers to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) before marketing a new drug. The NDA included a full list of the drug's components and composition, information about all clinical investigations, copies of both the packaging and labeling of the new drug, and methods of manufacture, facilities, and controls. The FDA also established a timeline to complete its safety evaluation and added a caveat to allow companies to proceed with marketing a new drug if they did not respond within 60 days. This process was designed to ensure that new drugs were safe before they were marketed but flaws were recognized and in 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act addressed some of these flaws. The amendments required drug manufacturers to provide more information about the safety and effectiveness of their drugs, and they gave the FDA more power to regulate the marketing of new drugs (U.S. Drug & Food Administration, 2018).

In 1943, the first double-blind clinical trial was conducted by the Medical Research Council (MRC) in the UK. The trial investigated patulin, a penicillin derivative, for treating the common cold. The trial was conducted by blinding the physicians and the patients from knowledge of who was receiving the treatment vs who was receiving the placebo. The results revealed no difference between the patients receiving treatment versus those receiving the placebo. In 1946, Austin Bradford Hill and Philip Hart conducted the first randomized control trial through the Medical Research Council for the treatment of tuberculosis with streptomycin. The trial showed that streptomycin was effective in treating tuberculosis, and it helped to establish the use of antibiotics in medicine and popularized the utilization of randomization in clinical trials (Nellhaus & Davies, 2017).

The 20th century was a pivotal one for clinical trials. In 1947 the Nuremberg Code was introduced following the Nuremberg trials in Germany where Nazi physicians were found to have conducted nonconsensual experiments on concentration camp prisoners including sterilization in an attempt to eliminate the Jewish race (United States Holocaust Memorial Museum, n.d.). The discovery of the *Tuskegee Study of Untreated Syphilis in the Negro Male* of the late 1930s led to the *Declaration of Helsinki* in 1964 (Goodyear et al., 2007) which led to the *Belmont Report* in 1978 (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014). Additionally, the development of the Health Insurance Portability and Accountability Act (HIPAA) (Meadows, 2006), MedWatch (Kessler et al., 1993), Good Clinical Practices (GCP) (Switula, 2000) as well as clinicaltrials.gov have been established during this century.

In the 21st century, clinical trials have become even more sophisticated. Innovative technologies, such as electronic data capture (EDC) and remote monitoring, have made it possible to conduct trials more efficiently and effectively. EDC is a system that allows researchers to collect data from participants electronically. This helps to reduce the amount of paperwork involved in trials, and it makes it easier to track the progress of participants (El Emam et al., 2009). Remote participant monitoring is a system that allows researchers to track the progress of participants remotely. This is done using devices such as wearable sensors and smartphones (Abiodun et al., 2022). Remote monitoring helps to make trials more convenient for participants, and it also helps to reduce the cost of trials (Davey, 2022).

Clinical trials are currently in flux. On the one hand, there has been a lot of progress in the development of new drugs and treatments. On the other hand, several challenges need to be addressed. One of the biggest challenges facing clinical trials is the increasing cost of drug development. The cost of bringing an innovative drug to the market is estimated to be in billions of dollars. This excessive cost is due to several factors, including the need for large clinical trials, the increasing complexity of drug development, and the regulatory requirements that need to be met (Islam et al., 2022). Another challenge facing clinical trials is recruiting patients, particularly when large numbers of patients or niche populations are required. This can lead to delays or even complete abandonment of the trial. Additionally, recruiting difficulties can also lead to higher costs as more resources are needed to obtain sufficient participants. This can be especially true for trials involving rare diseases or treatments (Donovan et al., 2016).

Despite these challenges, there is still a lot of progress being made in clinical trials. New drugs and treatments are developed constantly, and clinical trials are constantly evolving. Some recent trends in clinical trials include artificial intelligence (AI) and machine learning, patient-centered research, and remote monitoring of investigational sites for research. AI and machine learning improve clinical trial design and conduct (Weissler et al., 2021). AI can, for example, be used to identify patients most likely to benefit from innovative treatments. Additionally, it can be used to analyze clinical trial data more efficiently. Patients are placed at the center of the decision-making process with patient-centered research. A patient-centered approach involves working closely with patients to design and conduct clinical trials. Remote monitoring of clinical investigational sites is an innovative technology that enables study sponsors to monitor their studies' data and files remotely. Data can be checked and analyzed for accuracy, timeliness, and completeness.

Phases of Clinical Trials

Clinical trials are pivotal in ensuring both the safety and efficacy of the research product that is being developed. The structured and distinctly phased clinical trial process is meticulous and involves testing the research drug on human/patient volunteers. The entire process can take up to over a decade from the initial idea of the research drug from a scientist to bringing the drug to market. The phases of the clinical trials process are the preclinical phase/phase 0, phases 1, 2, 3, and 4. Each phase has its distinct purpose and involves the research drug to move through each phase, though a patient volunteer will only participate in one phase.

For this paper, the preclinical phase/phase 0 involves the testing agent in animal models for an initial idea of the therapeutics potency, side effects, and metabolism in the body. This phase is often conducted in translational labs. Phase 1 is the first phase of human research. The phase entails a small cohort of patient volunteers, often 15 to 50 depending on the trial, in which the primary focus is the safety of the research drug in humans. During this phase, patients are meticulously monitored for any adverse effects of the drug and identify the maximum tolerated dose (MTD), i.e., the highest dose tolerated without any severe side effects. Phase 2 builds on the safety data collected from Phase 1 and looks further into the potential therapeutic effects of the research drug. The phase usually involves less than one hundred patients and aims to assess the efficacy or ability of the drug to achieve the desired effect, i.e., shrinking a tumor or reducing symptoms. Different doses and administration schedules are explored during this phase to help determine the optimal treatment regimen for the research drug. With safety the priority, clues into the effectiveness of the drug for its intended use are collected. This data is valuable in the progression of the research drug into further phases of the clinical trial process.

Phase 3 is the most extensive and crucial phase in which definitive testing is done between a control group often receiving the current approved treatment or a placebo and compared to the treatment group that is receiving the research drug. Safety is monitored closely, and successfully being able to collect data to determine whether the drug's efficacy differs from those presently on the market is a significant milestone to potential regulatory approval by the FDA or other regulatory bodies. Once approval is obtained, Phase 4 trials can be executed. Often referred to as post-marketing surveillance, this phase allows for the identification of the long-term effects and side effects of the drug that could not be captured during the other clinical trial phases. Figure 1 captures the overview of the phases of clinical trials.

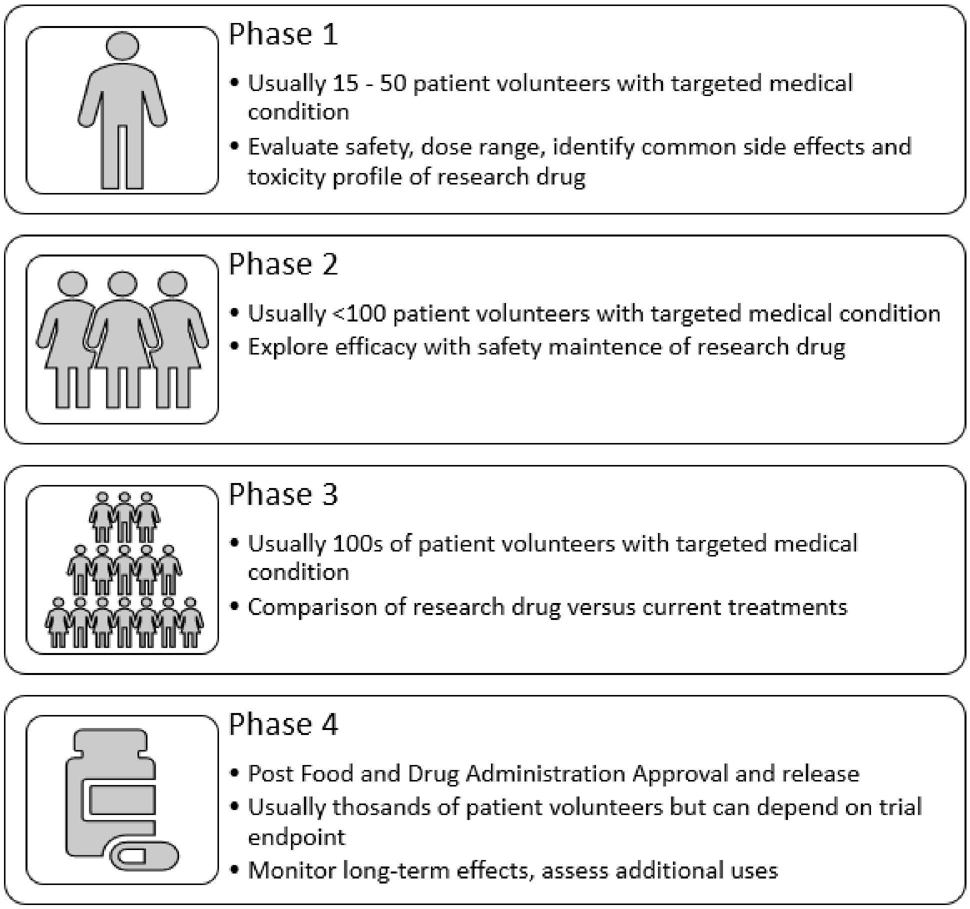

Figure 1. Phases of Clinical Trials. Adapted from MD Anderson Cancer Center (n.d.) Phases of Clinical Trials.

The process of clinical trials and its phases involves the collaboration of several stakeholders, i.e., researchers, pharmaceutical companies, regulatory agencies (FDA, etc.), clinical trial sites (hospitals, clinical or research centers), and volunteer participants. The researchers often design the product, and the trials as well as analyze and interpret the results of the data collected throughout the trial. The pharmaceutical companies sponsor and fund trials and in turn provide the resources and infrastructure for the study to be conducted successfully. Regulatory agencies priced ethical oversight to ensure that the trial is conducted appropriately, and data integrity and participant safety are protected throughout the process. Clinical trial sites, i.e. hospitals, clinics, etc., are where the trials are conducted with qualified medical personnel and research personnel to oversee patient care and the operational needs for the study conducted at the site.

Decentralized Clinical Trials

Decentralized clinical trials (DCTs), as novel as they may seem have been on the scene of clinical trials for the oncology space as early as 2002. But before discussing the history and literary implications, it is important to understand what is meant by the term decentralized clinical trials.

A traditional clinical trial model is one in which the researcher(s) will perform all necessary procedures of the study at a single site which is often a research center or hospital site. A decentralized clinical trial is defined by the Food and Drug Administration (FDA) as a clinical trial in which some or all clinical trial activities take place at a location other than an investigational site (U.S. Food & Drug Administration, 2023). According to the Decentralized Trials and Research Alliance (DTRA), a decentralized clinical trial is a clinical trial using technology, processes, or/or services designed to eliminate or reduce the need for a participant to physically go to a clinical trial site (Decentralized Trials & Research Alliance, n.d.). A decentralized clinical trial can be classified as fully decentralized or as a hybrid clinical trial. Clinical trials that are fully decentralized are executed in locations outside traditional trial sites. A hybrid clinical trial is defined by DTRA as a suitable scenario that partially eliminates the requirement for participants to visit a physical trial site to attend a protocol-required event previously conducted there. There are several hybrid trial types, including:

- *Hybrid By Site*: trials in which some participants take part at traditional research sites while others use decentralized research methods exclusively.
- *Hybrid By Visit*: Trials in which some visits require the participant to visit a traditional research site, while other visits can be conducted via decentralized methods (Apostolaros et al., 2020).

Figure 2 illustrates the models of clinical trials.

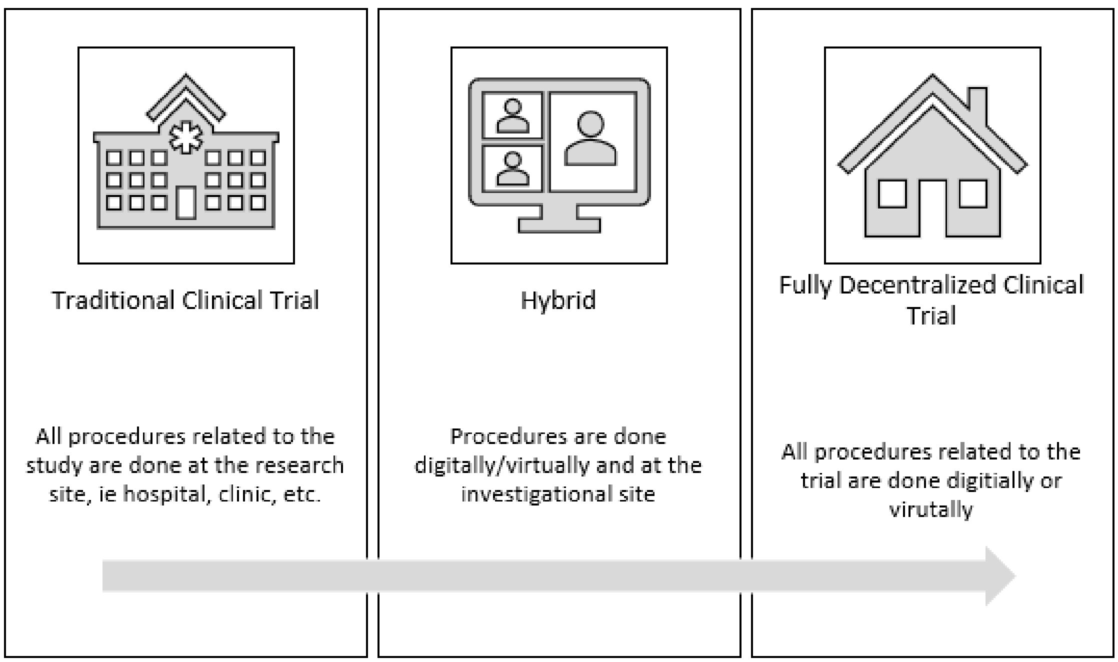

Figure 2. Operational Models for Clinical Trials. Adapted from Thomas et al., 2024.

The first fully decentralized clinical trial under an Investigational New Drug (IND), i.e., an FDA authorization request to utilize an investigational drug or biological product in humans, was executed in 2011 by Pfizer. The study, Research on Electronic Monitoring of Overactive Bladder Treatment (REMOTE), provided proof of the ability to conduct a clinical trial in a completely web-based platform with simplification of the screening process (Orri et al., 2014). The study was a phase 4 post-market surveillance study that did not pose the intensity that a phase 1 or 2 study might bring. Before REMOTE, studies had adopted hybrid decentralization models such as Lilly's 2002 phase III study, Magellan, which consisted of the administration of tadalafil in eighty male participants. The study was conducted using electronic consent, remote safety and efficacy monitoring, home shipment of the study drug, and electronically reported patient outcomes (Bionity.com, 2022; Park, 2023).

Embracing Decentralized Clinical Trials In The Face Of The Covid-19 Pandemic

The outbreak of the COVID-19 pandemic brought about an urgent need to accommodate patients participating in clinical trials, particularly those affected by rare diseases and conditions with high mortality and morbidity rates. However, prior to the pandemic, regulatory and operational challenges hindered the full realization of decentralized clinical trials (DCTs), preventing them from gaining significant momentum (Ferranti & Schattgen, 2022).

Between December 2019 and July 2021, non-COVID-related trials were deprioritized due to the overwhelming demand for resources and treatments related to the virus. As a result, approximately 1,473 clinical trials were terminated, suspended, or withdrawn, as reported by clinicaltrial.gov. The urgent quest for effective treatments against the pandemic led to a surge in COVID-19 clinical trials, with approximately 1,557 new studies initiated during this period, necessitating the reallocation, and refocusing of resources to combat the disease. This scenario posed a significant challenge for individuals with rare and multisystem diseases. In response, sponsors and investigational sites began transitioning to models that incorporated elements of decentralized clinical trials, such as telemedicine consultations, utilization of wearable devices, and the shipment of investigational drugs directly to patients' homes (Manjrekar et al., 2022).

The convergence of the pandemic's urgency and the need to provide accessible and effective treatments spurred the adoption of decentralized clinical trial approaches as a means to address the unique challenges posed by the crisis. By embracing decentralized clinical trials and integrating technologies that facilitate remote interactions and monitoring, researchers and healthcare providers aimed to ensure the continuity of clinical trials and enhance patient participation, particularly for those with complex and rare diseases.

The United States Food and Drug Administration's Evolving Stance On Decentralization in Clinical Trials

Before the pandemic, one of the biggest barriers to implementing decentralized clinical trials was the regulations surrounding the implementation of such models in clinical trials. In March 2020, the United States Food and Drug Administration issued the *Guidance for Industry, Investigators, and Institutional Review Boards on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic* which provided an opportunity for studies with prior institutional review board (IRB) and/or FDA approval to adapt COVID-19-related trial changes and utilization of telemedicine and virtual site platforms (Pollard et al., 2020).

In December 2021, the US FDA issued the *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations* which provided guidance on data collection and validation methods for wearables as well as prescription drug use-related software (PDURS) guidance. Decentralized clinical trials for drugs, biological products, and devices: guidelines for investigators, industry (pharmaceutical companies), and other stakeholders were suggested by the U.S. Food and Drug Administration (FDA) in March 2023. This guidance is intended to facilitate the widespread adoption of Decentralized Clinical Trials (DCTs) by pharmaceutical companies and to meet the requirements of the FDA's obligations under section 3606 (a) of the U.S. Food and Drug Administration's Office of Regulatory Affairs (FDAORA). The FDORA requires the FDA to adopt or amend guidance that is drafted to facilitate the advancement of the use of Decentralization of Clinical Trials for Drug and Device Development by December 29th, 2023, (Mohanty et al., 2023). The *Decentralized Clinical Trials for Drugs, Biological Products, and Devices: Guidance for Industry, Investigators, and Other Stakeholders* further gives guidance on the complexity of a trial that should be considered for a fully decentralized clinical trial as opposed to a hybrid model.

The FDA has identified over the last five years that the use of decentralized clinical trials can promote research on rare diseases, lessen the caregiver burden, improve the convenience of clinical trials for participants, and promote research diseases that affect populations with constrained mobility or get admission to standard trial websites. Moreover, decentralized clinical trials could enhance trial members' engagement, as well as the recruitment, enrollment, and retention of various diverse patient populations. Decentralized clinical trials also present specific demanding situations related to coordinating trial operational tasks among research teams and facilities positioned in locations outside of traditional investigational sites. For stakeholders such as sponsors, investigators, and others, the FDA guidance provides useful suggestions on drug and device development through decentralized clinical trial implementation.

Gaps in Existing Research for Investigational Sites

It can be implied by previous research that decentralized clinical trials bring value in both tangible and intangible ways to the pharmaceutical industry. Tangible values include an increase in drug program value, shorter study timelines, and a decrease in protocol amendments while intangible values include patient-centric trials that lead to an increase in patient engagement and adherence to studies. Studies have additionally acknowledged downs falls to decentralized clinical trials, i.e. patient preference for on-site conduct and digital limited access (Adesoye et al., 2023), and study phase consideration, i.e., phase 3 is more suited vs phase 1 (de Las Heras et al., 2022), when it comes to the investigational sites the biggest barrier assumed is the training of study staff by some (Reites, 2021a). While these values have direct effects on the pharmaceutical industry, a key element is the patients that are in these trials that are sourced from investigational sites.

Research has not yet focused on the value a decentralized clinical trial brings to an investigational site, i.e., a study site. These sites can consist of academic medical centers, community centers, clinics, and research centers. Mackinnon (2023) speaks on the components of decentralized clinical trials, i.e., telemedicine, application, and technology, wearable or connected devices, electronic consent, electronic clinical outcome assessments (eCOA), home healthcare, and direct-to-patient shipping. Figure 3 illustrates these components. These components require investment for the participating investigational site that often is outside a study budget or something that an industrial sponsor must provide financial support for (Virgil, 2023). These investments can often be expensive to initiate and maintain. Additionally, it can entail an extensive commitment of research personnel for initiation and varying degrees of training of research personnel at investigational sites. The goal of this study is to investigate the benefits of decentralized clinical trials for cancer centers, comparing the investment made and the return that the investment yields for both tangible and intangible measures of clinical trial success that revolve around the patients that drive the cost of clinical trials at investigational sites. Table 1 provides a summary of the literature regarding the value of decentralized clinical trials.

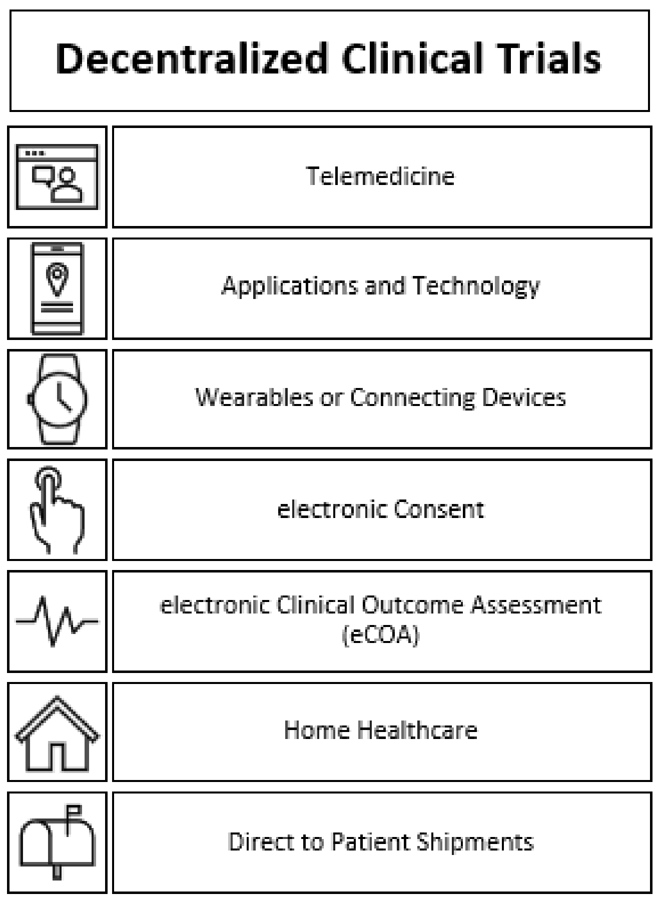

Figure 3. Elements of Decentralized Clinical Trials. Mackinnon (2023).

Table 1.
Literature Review of the Value of Decentralized Clinical Trials

	Definition of DCT	Perspective	Tangible Value	Intangible Value	Investigational Site Investment	Limitation
DiMasi et al., 2023	Fully decentralized or Hybrid	Pharmaceutical Industry	Y	Y	N	All operational aspects of clinical trials need to be analyzed
Dahne & Hawk, 2023	Fully decentralized or Hybrid	Investigational Site	N	Y	N	Tangible gains not of focus
Adesoye et al., 2023	Hybrid	Investigational Site	N	Y	Y	No focus on investment needs
Goodson et al., 2022	Hybrid	Investigational Site	N	Y	N	No focus on tangible value or investment
Licholai, 2022	Hybrid	Pharmaceutical Industry	Y	Y	N	Need to pool DCTs by type in analysis
Van Norman GA 2021	Fully decentralized or Hybrid	Investigational Site	N	Y	N	Site costs implied but overall trial cost of focus
Dorsey et al., 2020	Fully decentralized or Hybrid	Investigational Site	Y	Y	N	Tangible gains inferred
Khozin & Coravos, 2019	Hybrid	Investigational Site	N	Y	N	Focus on intangibles
Apostolaros et al., 2020	Fully decentralized	Pharmaceutical Industry	Y	N	N	Tangible gains inferred

A study conducted by the Tufts Center for The Study of Drug Development (CSDD) and Medable Incorporated in 2022 has shown that decentralized clinical trials are associated with reduced clinical trials timelines that have yielded a five to fourteen times net financial benefit versus traditional clinical trials (TCTs) for Phase II and Phase III trials. The financial benefits were shown to be associated with an increase in patient enrollments, lower rates of protocol amendments, and shorter study cycles, i.e., studies opening and closing at faster rates versus traditional clinical trials (DiMasi et al., 2023). While promising for pharmaceutical companies, the question remains: *How does digitalization, the foundation of decentralized clinical trials, impact the clinical trials offices that operationalize clinical trials at hospital/clinical sites?*

CHAPTER 2

STUDY 1 - ADOPTION OF DIGITALIZATION IN CLINICAL TRIAL OFFICE

Introduction

To get a better understanding of the thought process that evoked the question arising in this dissertation, it is vital to understand the limited literature published on the impact of decentralized clinical trials, particularly regarding the impact of digitalizing clinical trial offices in preparation for the ability to conduct and execute decentralized clinical trials. Not much has been researched to date on this matter, partially because of the resources available to conduct such studies and partially because of the oversight in considering the volume of work or effort that clinical trials offices need to invest in facilitating decentralized clinical trials. This chapter focuses on answering the question: *How does digital adoption impact the staff of clinical trials offices and patient accruals for the trials these offices support?*

Literature Review

The Tufts Center for the Study of Drug Development (CSDD) researched to assess the benefits of decentralized clinical trials to help research and development (R&D) sponsors determine the worth of investing financially and allocating resources to sponsor the implementation of decentralized clinical trial elements (DiMasi et al., 2023). For the study, the researchers deployed an expected net present value (eNPV) model to assess the financial impact that was based on an earlier model deployed (Levitan et al., 2018).

The main findings DiMasi et al (2023) found in the study are that decentralized clinical trial (DCT) methods can provide substantial financial value in drug development and commercialization, particularly in phase II and phase III trials. (Licholai, 2022). The findings suggest that decentralized clinical trial methods can be a valuable tool for improving the efficiency and cost-effectiveness of clinical trials. The increase in the value of drug development associated with decentralized clinical trials (DCTs) is primarily due to reductions in phase cycle times. According to the study, the value of utilizing decentralized clinical trial methods is driven by declines in screen failure rates, declines in phase durations, and decreases in substantive protocol amendments. However, taking into consideration the costs of implementing decentralized clinical trials, fewer protocol amendments, and reductions in screen failure rates did not suffice on their own for a net financial benefit even though these factors contributed to sponsor financial benefits (DiMasi et al., 2023).

DiMasi et al. (2023) acknowledge that the decentralized clinical trial adoption experience is promising though still in its early stages. They suggest that future research should focus on investigating relevant aspects of clinical trial operations where there is currently not adequate data. These aspects include the generalizability of the patient population, drug dose adherence, automated data collection, automated communication, and data monitoring efficiencies. The authors further remark that the benefits evaluated in this study are mainly for pharmaceutical companies. Furthermore, they imply that the social benefits of implementing decentralized clinical trial approaches consist of advantages experienced by trial participants, such as enhanced access and convenience, as well as likely higher participant gratification from remote tracking capabilities which cannot be offered without comprehensive clinical assistance time (DiMasi et al., 2023).

Studies speak on the value of patient engagement (Levitan et al., 2018), patient accrual (Galsky et al., 2015), and non-financial drivers such as diversification of clinical trials accruals (Dahne & Hawk Jr, 2023; Goodson et al., 2022). According to Levitan et al (2018), the key contributors to value are time, revenue, risk, costs, and intangibles; these are elements that may not necessarily have a direct monetary worth but can still impact the total value of the project. The ENPV for a pre-phase 2 study is an increase in NPV of $62 million ($65 million for pre-phase 3) and an increase in ENPV of $35 million ($75 million for pre-phase 3), the overall effect of a patient engagement activity that avoids one protocol amendment and improves enrollment, adherence, and retention. These values indicate the value added to the project through patient engagement activities (Levitan et al., 2018).

Staff Turnover in Clinical Trial Offices

With an impact on efficiency, trial continuity, and patient safety, staffing turnover is another persistent challenge faced by clinical trials offices and clinical research organizations (CROs). Clinical research associate (CRA) turnover rates reached as high as 30% in 2020 according to the CRO Industry Global Compensation & Turnover Survey conducted by BDO in 2021. The roles of a clinical research associate, research assistant, or clinical research coordinator that is encompassed in the survey require a facet of skills that include knowledge of disease state, attention to detail, interpersonal skills, project management, regulation, and protocol knowledge as well as IT and meticulous documentation maintenance. Along with these skillsets, demanding hours, high-pressure environments, tight deadlines, and tasks that often seem repetitive and compensation that is not often as competitive as that of industry can lead to further feelings of stagnation and low job satisfaction. With the expectations of these skillsets to conduct their roles successfully, burnout is inevitable with 67.7% stating stress adversely affects their work performance (BDO, 2021).

Staff turnover in clinical trials offices has a significant negative consequence. Experience staff members take valuable institutional knowledge with them as well as expertise that hinders clinical trial operational efficiency (Sun et al., 2023). Patient care continuity is disrupted, and patient safety is at threat as new staff are being trained and onboarded (Bridgeman et al., 2018). Another driver of patient accrual and retention (Jackson et al., 2003) in clinical trials is the trust they develop with the clinical trial staff on trials. The turnover of staff not only impacts the relationship patients develop but also threatens mistrust and the overall patient experience (Salvagioni et al., 2017). The integrity of clinical trials is further impacted by the potential quality of data collection with an increase in risk of data entry compliance and integrity (Bridgeman et al., 2018). Adverse event reporting, eligibility patient enrollment opportunities, and delayed regulatory filings could lead to research site extensions to meet recruitment goals and delays for study sponsors that can cost sponsors upward of thousands to millions of dollars per day (Briel et al., 2021; Myers et al., 2019).

Clinical research trials rely on research participants to generate the data needed to achieve a successful trial. What is referred to as a fundamentally human enterprise (Igbinadolor et al., 2022), the move to decentralized clinical trials becomes more prominent, the roles clinical research team staff and physicians play in the bond with research participants continue to play a vital role in participant trust (NCATS, 2024). Digitalization is not implemented to replace research staff but to help clinical research team staff grow in their professional paths and provide an avenue to help facilitate the efficiency of work and prevent burnout. The right technology can help enhance workflow efficiency by providing a means to automate redundant tasks and allowing staff to focus on higher-value activities and improve job satisfaction. Furthermore, digitalization allows for opportunities for more flexibility at work through remote options such as remote monitoring, telemedicine visits, and data collection.

Minority Patients in Clinical Trials

In 2020, amongst thirty-two thousand participants in clinical trials in the United States, only 8% percent were reported as Black and 11% Hispanic (Kelsey et al., 2022a). The 2020 U.S. Census revealed that the population consisted of 12.1% Black and 18.7% Hispanic (Jensen et al., 2021) which revealed a major underrepresentation of two important demographic groups in clinical trials further highlighting a persistent challenge for clinical trials. Lack of diversity within clinical trials has a potentially significant consequence of the development of treatments without diverse population data leading to a lack of generalizability and effectiveness of treatments for an inclusive patient population (Fink et al., 2022). This review explores the minority participation in clinical trials, highlights perceived barriers, and the potential that digitalization of clinical trials offices processes and in turn the facilitation of decentralized clinical trials can help bridge these gaps.

The underrepresentation of minority patients in clinical is attributed to several factors. Logistical hurdles created by social determinants such as poverty (G. E. Lee et al., 2016) and limited access to healthcare (Barrett et al., 2020; Caldieraro-Bentley et al., 2018) contribute to underrepresentation. Deep-rooted historical mistrust (Smirnoff et al., 2018) in the healthcare system from earlier unethical research practices (Nature, 2020) has brought on a stigma for minority communities in regard to clinical trials. Cultural insensitive communication (Morgan et al., 2024), language barriers (Haley et al., 2017; Wong et al., 2020), and restrictive eligibility criteria (Kelsey et al., 2022) to participate in clinical trials are other factors that have unintentionally restricted minority patient participation in clinical trials. Another barrier is a geographic barrier since trials are often concentrated around academic medical centers posing an issue for geographically dispersed minority groups and populations (Acuña-Villaorduña et al., 2023; Beltrami et al., 2023; H. Lee et al., 2024).

Decentralized clinical trials and the digitalization of clinical trials offer a solution to bridge gaps in minority population participation in clinical trials. Digital platforms offer the ability to improve outreach and education by providing an avenue to develop culturally appropriate and targeted outreach materials in multiple languages (Hardy-Werbin et al., 2023). Digital platforms also facilitate ongoing education and information to participants throughout trials which would foster trust and open communication through the trial process. Digital screening tools and recruitment platforms can streamline enrollment processes by providing more accessibility and convenience for geographically dispersed populations (Weiner et al., 2023). Telemedicine (Hardy-Abeloos et al., 2023) and remote monitoring technologies (Battelino et al., 2023; Blood et al., 2023) can further eliminate geographical barriers by allowing patients to participate from the comfort of their homes or local clinics without the burden of traveling long distances to research sites (Ghafar-Zadeh, 2015; Malwade et al., 2018). This facilitates accessibility in underserved areas. Digital tools can further facilitate the collection of data needed to analyze and help identify barriers and ensure equitable access to research opportunities (Koydemir & Ozcan, 2018).

Digitalization of clinical trials offices holds immense potential to improve minority participation in clinical trials. By addressing barriers and leveraging the strengths of digital technologies, a future where clinical trials are truly inclusive, reflecting the diversity of the population they aim to serve seems more tangible to achieve. This will ultimately lead to more effective treatments and improved health outcomes for all.

Conceptual Framework And Hypotheses

Based on Dimasi's published findings in 2023 and the lack of literature on the impact of the digitalization of clinical trials offices to accommodate decentralized clinical trials, the conceptual framework was developed to investigate the value of digitalization of clinical trial offices and processes to accommodate decentralized clinical trials (DCTs) from the perspective of research sites. This conceptual framework will aim to investigate how the adoption of digital tools and systems drives patient elements in clinical trials and operational teams that run the clinical trials. The outcome variables included improvement in minority patient accrual in clinical trials and turnover of staff in clinical trial offices.

For the facilitation of decentralized clinical trials, it is essential that clinical trials offices incorporate digital tools and systems. This provides an ability to allow for resources and tools to assist in patient recruitment, patient consent, data collection, and other regulatory and operational tasks (Kotecha et al., 2023). For the purposes of this paper, the adoption of digitalization is defined as incorporating at least one digital modality into the clinical trials office for a minimum of a year.

Turnover Of Research Teams

Morale as defined by the Cambridge Business English Dictionary is “the level of satisfaction felt by a person or group of who work together.” This seemingly simple word in the context of its employees is a company’s most prized possession. In other words, one’s satisfaction in what they do, feelings of well-being toward the company (Muskita & Kazimoto, 2017), motivated job engagement (Verma & Kesari, 2020) and the emotional connection employees have during their time within a workplace environment based on the risk, policies, and management (Bhasin, 2018; Webster, 2018). According to Gallup (2019), disengaged employees cost US $483 Billion to $605 Billion in lost productivity yearly. This cost accounted for employee turnover, productivity loss, and decreased quality of organizational outcomes (Hickman & Pietrocini, 2022).

In 2021, Professor Anthony Klotz introduced the term “The Great Resignation” to account for the significant increase in the number of people leaving their jobs since the COVID-19 pandemic started in early 2020 (Henry, 2021). According to the PwC’s Global Workforce Hopes and Fear Survey (2022), “job fulfillment and ability to be one’s true self at work” were amongst the top three reasons for an employee to consider a job change. While financial incentives continue to be the top reason an employee leaves a particular employer, morale is the key to keeping an employee from starting the search. (PricewaterhouseCoopers. (n.d.)., 2022)

Traditional clinical trials, often inundated with paper-based processes and logistical hurdles, are undergoing a transformative shift. The adoption of digital tools stands at the front of this shift with the looming promise of aiding research team efficiency and cultivating a more positive workforce. This hypothesis rests on several compelling arguments rooted in streamlining workflows, enhancing data quality, and fostering deeper engagement with participants.

Digital tools like Electronic Data Capture (EDC) systems are thought to eliminate the inherent errors and delays associated with paper-based data collection. Data is captured electronically at the source, minimizing transcription errors, and expediting aggregation for analysis. This improves data quality and allows researchers to alleviate administrative burdens, allowing time to focus on deeper insights and strategic decision-making. Digital solutions like secure messaging platforms and video conferencing tools foster seamless communication and collaboration between researchers, sponsors, and participants (Mittermaier et al., 2023; Vial, 2023). This overcomes geographical barriers and facilitates real-time information exchange, accelerating trial activities and streamlining the overall workflow.

The adoption of digital tools in clinical trials presents a compelling opportunity to enhance research team efficiency across various stages of the study. From streamlined data capture and improved communication to increased participant engagement and real-time data insights, these tools hold the potential to revolutionize the clinical research landscape, ultimately accelerating the development of new therapies and improving patient outcomes (Barton, 2022). While careful planning and robust infrastructure are crucial for successful implementation, the potential benefits of this digital transformation are undeniable, paving the way for a more efficient, data-driven, and ultimately, successful future and retention for clinical trial office staff. This led to the first hypothesis tested:

HYPOTHESIS 1 (H_1): *The adoption of digital tools for clinical trials is associated with reduction in the turnover of research staff.*

Accrual Of Minority Patients

Sanofi has reported that 70% of prospective patients for trials live over two hours from clinical sites (Abdulai, 2021). The importance given to diversification of the reach of clinical trials that have historically only been accessible to those who lived within a certain distance from clinical sites was given much prominence during the pandemic. The assumption was made that decentralized clinical trials for an oncology trial would lead to an increase in trial accruals. Insufficient or delayed accruals to clinical trials account for 40% of the usage of the clinical trials budget (Reites, 2021b). Based on this, to understand the financial value of implementing decentralized clinical trials for cancer centers, patient accruals on decentralized clinical trials versus traditional clinical trials need to be researched. A major cause of delays in accrual goals is operational insufficiencies, i.e., longer study start-up timelines, which leads to a cancer center not having an appropriate trial to offer potential study participants or trials being closed before institutional approval.

Clinical trials evaluate the safety and efficacy of novel treatments. It is essential that clinical trials include people of various backgrounds such as race, ethnicity, and biological sex to help ensure all communities benefit from the drugs that are developed through trials (NIMHD, 2024). Minority representation is a problem that has plagued clinical trials for centuries. Mistrust stemmed from historical atrocities and incidents that included the U.S. Public Health Service Syphilis Study at Tuskegee between 1932 and 1972 (CDC.gov, 2022) the Arizona Board of Regents and Arizona State University's improper utilization of DNA samples without the Havasupai Tribe member permissions (Garrison, 2013) and the infamous Henrietta Lacks case (Khan, 2011).

To level this lack of minority representation in clinical trials, the FDA developed guidance with the aim of enrolling underrepresented ethnic and racial populations in clinical trials (FDA, 2023). Further, the Cancer Moonshot initiative through President Biden's initiative incorporates a goal of addressing inequities in cancer care and ensuring access to cutting-edge diagnostics, therapeutics, and clinical trials (WH.GOV, 2022). The National Institute of Health has also released guidelines for the inclusion of minority populations in clinical trials (*NIH Guidelines*, n.d.). Researchers are making strives to engage communities and community leaders to encourage trust and undo the stigmas of the past (Gray et al., 2021; Reopell et al., 2023).

For research sites, operational processes that drive the cost of clinical trials include administrative processes, i.e., study start-up, and the workforce. Operational efficiency leads to a reduction in trial timelines which is a major driver of costs for clinical trials (Reites, 2021b). The reduction in specifically the study-startup timeline would be expected to affect patient accruals to clinical trials at decentralized clinical trials.

While patient enrollment drives cost, the key is keeping patients on trial (Sertkaya et al., 2014). The role of decentralized clinical trials on the retention rates of patients at a cancer center is a driver of the financial benefit the cancer center obtains through a clinical trial. These financial benefits can be both tangible (per patient cost collected) and non-tangible (increase in study completion timelines).

Patient retention in clinical trials directly correlates with the success of clinical trials. If patients do not stay on a trial long enough it can lead to an early and wasted end of the trial. This is budgeted dollars that an investigational site is no longer receiving to cover the costs of operational, regulatory, and clinical tasks that are accounted for to ensure there is a benefit financially for the cancer site in conducting the trial (Lièvre et al., 2001). Decentralized clinical trials, while mostly hybrid at cancer sites, are also linked with more accessibility for patients to needed procedures for trials but the question needs to be posed as to what the advantages of this would be for those with cancer that often need more direct access to hospitals and centers for adverse events that might arise during treatment on trial. One major driver of patient retention is the adverse effects the patient feels while on a clinical trial therefore researched with this hypothesis (Poongothai et al., 2023). Unsuccessful trials affect patient treatment options for the future and while not a direct financial effect one to consider for future morbidity and mortality rates for cancer centers.

For decentralized clinical trials to be possible, tools need to be incorporated at research sites to accommodate minority patients to be screened, treated and followed off-site. Tools such as electronic consent forms, wearable devices, remote monitoring technologies, and translational technologies can help overcome geographical and financial burdens that are often barriers for patients to participate in trials (Ahluwalia, 2021; Winkfield et al., 2021). This led to the second hypothesis tested:

HYPOTHESIS 2 (H_2): *The adoption of digital tools for clinical trials is associated with improvement in the accrual of minority patients on clinical trials.*

The independent variable of *adoption of digital tools* was utilized with the dependent variable of (H_1) *turnover of research staff* and (H_2) *accrual of minority patients*. Controls were incorporated into the model to account for the effects of certain clinical trials office characteristics, i.e. location and type of cancer center on the model. The proposed conceptual framework is summarized in Figure 4.

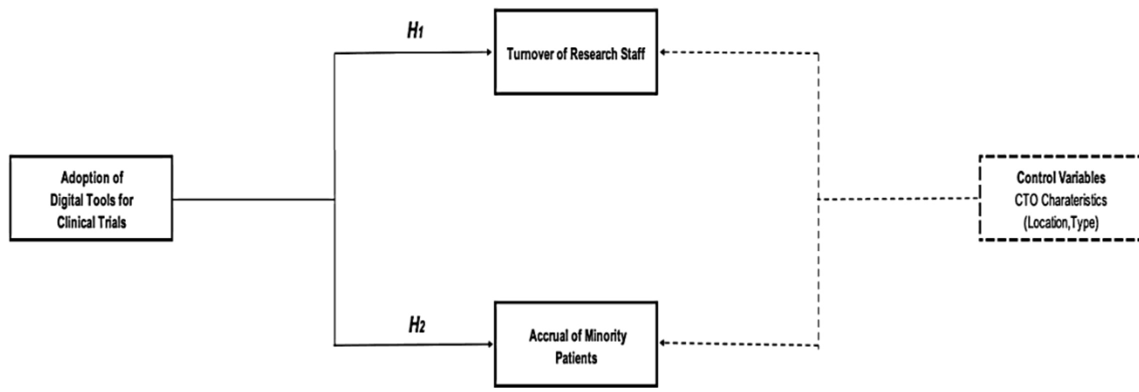

Figure 4. Conceptual Model for Digital Adoption in Clinical Trials Offices.

Research Method

The research adopted a quantitative technique to understand the value of digitalization of clinical trials offices for clinical trial operational staff and teams through structured surveys. This methodological approach allowed for the examination of both measurable outcomes. Structured surveys allowed for a systemic approach to data collection and standardized responses that could be quantified. The goal was to give an avenue for statically analyzable data that would not be possible with open-ended interviews or observations. Structured surveys also allow for pattern assessment, observing trends in data and associations across diverse groups of respondents.

Survey Design

The survey was developed through pilot groups in a three-stage approach. Pilot groups consisted of individuals who had previously worked at research sites as administrators, coordinators, or managers. This group was chosen based on their previous experiences with sites as well as their understanding of the perspective of sites when it comes to question structure and content. The first stage consisted of five peers who were tasked with reviewing the survey and providing feedback on the question content. While all feedback was encouraged, common themes or feedback were incorporated into the survey. In this stage, feedback-defining terms were a common theme. The terms in question were *administrator*, *diverse patient population*, *accrual*, *patient engagement*, and *patient retention*. The term administrator was defined as *a senior-level- management responsible for overseeing the overall operations, finances, and strategic decisions of the clinical trial office*. The term *diverse patient populations* was changed to *minority patients*, with the term being defined *as those that identified as Black or African American, Hispanic, Asian, and other*. Accrual was defined as the *signing of consent and the start of treatment*. Patient engagement was defined as *compliance with study procedures* and patient retention was defined as *remaining on and completing a clinical trial*. Questions about changes over increments of 1, 2, and 5 years were eliminated as redundances were noted.

The second stage of peer review consisted of the initial five as well as five additional reviewers. During this phase, question structure was the focus. Likert scale question models were questioned and restructured from sliding scales to multiple-choice questions. The choices for questions initially consisted of nine options - *strongly decreased, moderately decreased, slightly decreased, very slightly decreased, not changed, very slightly increased, slightly increased, moderately increased, and strongly increased*. Feedback was received about the confusion between *very slightly increased* and *very slightly decreased*. The option was eliminated, and questions were reduced to seven options. Mobile friendliness of questions was also noted with dropdown questions being minimized to not more than five options as well as a preference for multiple-choice options when possible.

The third stage included ten new pilot group participants that consisted of previous administrators at research sites as well as a digitalization vendor that works closely with research sites. The vendor was chosen to provide insight from an outsider's perspective to understand what site vendors, clinical research organizations and industry partners might benefit from the survey. Questions were additionally refined to include additional options for questions on types of digital tools that sites were incorporating and including questions on pros and cons with implementation. The postal code was eliminated and replaced with the question "Describe the location of your CTO/RO (research office)" with choices of *urban/city, suburban (outskirts of a city), rural,* and *other* answer options. Time for survey completion was noted with the average being twelve minutes for the average user. Additionally, the research office was also added to the survey to capture various research site structural models, and the suggestion was made to keep the survey anonymous to maximize participation.

The final survey was generated using Qualtrics software (Provo, Utah) and included about twenty-five questions that asked about sites, the impact of digital tools regarding patients as well as the office and its budget. The survey addressed cancer center demographics, level and tools incorporated for digitalization of the clinical trials office, study portfolios of the office, estimate office budgets and staffing/operational trends as well as patient trends since the implementation of digital tools in the clinical trials office.

Data Collection

The survey was sent to the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) listserv which comprised 650 subscribers from eighty-two academic and National Cancer Institute (NCI) designated cancer centers in North America at the time of the survey. The listserv serves as a resource available to clinical trials office staff to discuss best practices, solutions, and challenges that sites might be facing. The survey was sent out to the listserv on March 20, 2024. Three reminders were sent to the listserv to encourage participation and completion of the survey. There were no incentives for participation and participation was anonymous. The survey ran through July 1, 2024. The participation rate for the survey was 25% with 160 respondents.

The research adopted a quantitative technique to understand the value of digitalization of clinical trials offices for clinical trial operational staff and teams through structured surveys. This methodological approach allowed for the examination of both measurable outcomes. Structured surveys allowed for a systemic approach to data collection and standardized responses that could be quantified. The goal was to give an avenue for statically analyzable data that would not be possible with open-ended interviews or observations. Structured surveys also allow for pattern assessment, observing trends in data and associations across diverse groups of respondents.

Measures

For H_1 dependent variable *Staff Turnover*, respondents were asked the extent to which digitalization had impacted the staffing of the clinical trials office on the turnover of clinical trials office/research staff with seven answer options ranging from strongly decreased to strongly increased. Turnover was defined as the number of employees leaving. For H_2 dependent variable *Minority Patient Accrual*, respondents were asked what was observed since the implementation of digital tools for minority patient accruals on clinical trials with seven answer options ranging from strongly decreased to strongly increased. Minority patients were defined as those who identified as Black or African American, Hispanic, Asian, and other. Patient Accrual was defined as those who signed consent and started treatment. To capture the independent variable of *Digital Tool Adoption*, respondents were asked to what extent the clinical trials office adopted digital tools or systems to enhance processes (E.g.: eReg binders, eConsent platforms, wearable devices, screening tools, etc.). Answer options for the question included seven options that ranged from no extent (no digital tools or systems adopted) to completely (fully embraced in which the organization had integrated digital technologies seamlessly into its operations, leading to optimal efficiency and outcomes in clinical trials). In Table 2, variables are explained with questions asked and answer options included.

Table 2.
Variable Operationalization (Study 1)

Variable	Question	Options
Digital Tool Adoption	To the best of your knowledge, to what extent has the Clinical Trials Office (CTO)/research office adopted digital tools or systems to enhance processes? (e.g.: eReg binders, eConsent platforms, wearable devices, screening tools, etc.)	No extent: no digital tools or systems adopted. Very minimally: There may be some initial exploration or pilot projects, but the overall adoption is limited. Minimally: Some steps have been taken towards adopting digital tools or systems for clinical trial processes, but the implementation is limited in scope and impact. Moderately: There are some initiatives in place, but there is room for further expansion and integration. Significantly: There is a substantial investment in digital technologies, leading to noticeable improvements in efficiency and effectiveness. Very significantly: There are transformative changes in clinical trial processes. The organization is a leader in leveraging digital technologies for enhancing trials. Completely: Fully embraced. The organization has integrated digital technologies seamlessly into its operations, leading to optimal efficiency and outcomes in clinical trials.
Staff Turnover	As best you can, please answer the following on the extent to which digitalization has impacted the staffing of the CTO/RO on the following: Turnover of clinical trials office/research staff (Turnover = number of employees leaving)	1=Strongly decreased; 2=Moderately decreased; 3=Slightly decreased; 4=Not changed; 5=Slightly increased; 6=Moderately increased; 7=Strongly increased

Table 2.
(continued)

Minority Patient Accrual	To the best of your knowledge, since the implementation of digital tools, minority patient accruals on clinical trials has: (Patient Accrual = signed consent and started treatment)	1=Strongly decreased; 2=Moderately decreased; 3=Slightly decreased; 4=Not changed; 5=Slightly increased; 6=Moderately increased; 7=Strongly increased
Location	Describe the location of your CTO/RO.	Urban/City; Suburban (outskirts of a city); Rural; Other
Type of Institute	Which of the following best describes the type of institution you represent?	Academic medical center - Non-designated; Academic medical center - National Cancer Institute (NCI) Designated; Freestanding cancer center dedicated solely to cancer research and care; Government laboratory or private research institute focused on cancer research; Hospital or clinic without a formal designation as a cancer center

Data Analyses

The dependent variables of minority patient accrual and staff turnover were tested for normality. The correlation between implementation of digital tools adoption with staffing turnover was Pearson's correlation and minority patient accrual was estimated utilizing Spearman's correlation. Linear regression was employed to further evaluate the relationship between digital tool adoption, staff turnover, and minority patient accrual respectively with the ability to control for location of the clinical trials office and the institution type. Analyses were performed using SPSS statistical software, version 28 (IBM Corp., Armonk, NY).

Results

Listwise deletion was implemented for all the analyses conducted in this study and subsequently, the number of respondents shows variation with various analyses conducted on the data. For analysis of the respondents for the study, eighty-eight respondents were captured for demographics based on the dependent and independent variables being tested. Forty-six (52.3%) of these respondents were administrators, which was defined as senior-level management responsible for overseeing the overall operations, finances, and strategic direction of the clinical trials office. Twenty-four (27.3%) were research managers or supervisors while the remaining respondents consisted of seven research coordinators/data specialists, ten respondents that did not fit the categories list and were classified as *Other,* and one associate director/medical director. Respondents represented sixty-three (71.6%) National Cancer Institute (NCI) designated academic centers, twenty-one (23.9%) non-NCI academic centers, and four (4.5%) freestanding cancer centers that were solely dedicated to cancer research and care. Location of the institutions in which the clinical trial office locations included 65 (73.9%) in an urban/city setting, eleven (12.5%) in suburbs, three (3.4%) in rural areas, two (2.3%) in other areas and seven (7.9%) were blank. In Table 3, the characteristics of survey respondents are summarized.

Table 3.
Characteristics of Survey Respondents (Study 1)

Characteristic	Response	N (%)
CTO Role	Associate Director/Medical Director	1 (1.1)
	Administrator	46 (52.3)
	Research Manager/Supervisor	24 (27.3)
	Research Coordinator/Data Specialist	7 (7.9)
	Other	10 (11.4)
Institution	Academic – NCI-designated	63 (71.6)
	Academic non-NCI designated	21 (23.9)
	Freestanding Cancer Center	4 (4.5)
Location	Rural	3 (3.4)
	Suburb	11 (12.5)
	Urban/City	65 (73.9)
	Other	2 (2.3)
	Blank	7 (7.9)

N = 88; listwise deletion utilized for DV and IV combined

Variable Testing

The descriptive statistics for the independent variable "Digital Tool Adoption" revealed that most respondents (38.6%) had felt that their clinical trials offices had moderately implemented digital tools. The term moderately was defined as having some initiatives in place, but there is room for further expansion and integration. 34.1% of respondents had reported that they felt that their clinical trials office had significantly implemented digital tools to the extent that there was a substantial investment in digital technologies, leading to noticeable improvements in efficiency and effectiveness.

The descriptive statistics for the dependent variable "Staff Turnover" revealed that most respondents (48.9%) felt that the turnover of staff had not changed since the implementation of digital tools in the clinical trials office. 20.5% of respondents reported that the turnover slightly decreased, while 14.8% observed a slight increase in staff turnover.

The descriptive statistics for the variable "Minority Accrual" revealed that the majority of respondents (76.1%) felt that minority accruals had not changed since the implementation of digital tools in the clinical trials office. 15.9 % of respondents reported a slight increase in minority accruals while 3.4% reported a moderate increase. In Table 4, a summary of all the statistics of all the variables are summarized with the variables of digital tool adoption and staff turnover assumed to be of normal distribution and minority accrual showing a positive skew in distribution.

Table 4.
Variable Summary Statistics (Study 1)

		Digital Tool Adoption	Staffing Turnover	Minority Patient Accrual
MEAN (SD)		4.65 (.983)	4.83 (1.85)	4.16 (.623)
MEDIAN		5.00	5.00	4.00
SKEWNESS (SE)		-.053 (.257)	.178 (.257)	.172 (.257)
KURTOSIS (SE)		.229 (.508)	-.064 (.508)	4.132 (.508)
Kolmogorov-Smirnov	Statistic	.211	.247	.408
	df	88	88	88
	Sig.	<.001	<.001	<.001
Shapiro-Wilk	Statistic	.903	.903	.653
	df	88	88	88
	Sig.	<.001	<.001	<.001

Hypotheses Testing

The normality of the variables of *staff turnover* and *minority patient accrual* was assessed using the Kolmogorov-Smirnov (K-S) test and the Shapiro-Wilk (S-W) test. The K-S and S-W for the variables of *staff turnover* ($p < .001$) was significant for both K-S and S-W but considering the skewness and kurtosis were less than one, a normal distribution is presumed despite the K-S and S-W results. For *minority patient accrual* ($p < .001$) both K-S and S-W were significant, and kurtosis was greater than one indicating a non-parametric distribution and remained persistent despite transformation attempts. Pearson's correlation was utilized for staff turnover and Spearman's correlation was utilized for minority patient accrual to test the hypotheses. In Table 5, the correlation statistics are summarized which utilize listwise deletion in the analysis therefore capturing ninety-three respondents for the analyses.

Table 5.
Correlation Statistics (Study 1)

Pearson's Correlation		Digital Tool Adoption
Staff Turnover (N=93)	Correlation Coefficient	-.237
	Sig. (2-tailed)	.022
Spearman's rho		**Digital Tool Adoption**
Minority Patient Accrual (N=93)	Correlation Coefficient	-.105
	Sig. (2-tailed)	.326

H_1: The adoption of digital tools for clinical trials is associated with a reduction in the turnover of research teams.

The correlation coefficient between the variables of *digital tool adoption* and *staff turnover* is -0.237, indicating an inverse relationship. The significance level (p-value) is 0.022 which is less than the threshold of 0.05, so we reject the null hypothesis of no correlation. The results suggest a negative correlation between the perceived level of digital tool adoption and the turnover rate in the clinical trials office. There is a weak tendency for offices with higher clinical trials office adoption scores to have lower turnover rates, but this relationship is statistically significant and suggests that there is less than a 2.2% chance this correlation was observed at random.

$$\textit{Staff Turnover}_i = \beta_0 + \beta_1(\textit{Urban/City})_i + \beta_2(\textit{Suburban})_i + \beta_3(\textit{Other})_i + \beta_4(\textit{Digital Tool Adoption})_i + \beta_5(\textit{Academic medical center – Non designated})_i + \beta_6(\text{Freestanding cancer center})_i + \varepsilon_i$$

A linear regression was employed to investigate the relationship between digital tool adoption and staff turnover at clinical trials offices. The model included the following independent variable: *Digital Tool Adoption* (numerical) and the control variables for clinical trials office location (categorical): *Urban/City* (binary), *Suburban* (outskirts of a city) (binary), and *Other* (reference category) and institution type: *Freestanding cancer center* (binary) and *Academic medical center - Non designated* (binary). The model excluded the variable *Academic medical center - National Cancer Institute (NCI) Designated* due to multicollinearity (high correlation with other included variables).

The model employed for H_1 explained again a modest (13.1%), but a non-significant proportion of the variance in staff turnover ($F = 1.987$, $p = .77$). The coefficients table revealed no statistically significant individual variable at the alpha level of 0.05. Freestanding cancer centers tended to have higher staff turnover ($\beta = .198$, $p = .083$) but this effect was not significant. Non-designated academic medical centers did not show a significant difference ($\beta = .055$, $p = .621$). Urban ($\beta = .034$, $p = .787$) and rural locations ($\beta = .089$, $p = .450$) showed trends towards lower staff turnover compared to the reference category (*Other*), but these were not statistically significant. The model excluded the variables suburban and academic medical center – NCI designated due to multicollinearity (high correlation with other included variables). There was a trend toward a negative association between digital tool adoption and staff turnover ($\beta = -.249$, $p = .022$). Institutions with higher digital tool adoption tended to have lower staff turnover, which was statistically significant. In Table 6, the model statistics are summarized in which eight-six respondents were captured utilizing listwise deletion for the analysis.

Table 6.
Regression Coefficients for Explaining Staff Turnover

	B (SE)	β	ι	ρ
Digital Tool Adoption	-.465 (.199)	-.249	-2.331	.022
Urban	.162 (.599)	.034	.271	.787
Rural	.849 (1.177)	.089	.760	.450
Other	1.364 (.1.492)	.112	.915	.363
Academic medical center - Non designated	.239 (.481)	.055	.497	.621
Freestanding Cancer Center	1.734 (.987)	.198	1.757	.083
Constant	6.629 (1.140)		5.817	<.001

Note: R^2 = .131 (N = 86, p = .077)

The hypothesis aimed to understand if digital tool adoption would correlate to staff turnover. Since the location of a clinical trials office could play to the accessibility of minority populations and the type of institution could play towards resource availability, these variables were evaluated to understand the relationship. While the model captured a modest, significant, portion of the variance, none of the individual location-based variables reached statistical significance. Freestanding cancer centers showed higher staff turnover as compared to non-designated academic medical centers which has a marginal significance.

H_2: The adoption of digital tools for clinical trials is associated with improvement in the accrual of minority patients on clinical trials.

The correlation coefficient between the variables of *digital tool adoption* and *minority patient accrual* is -0.105 indicating an inverse relationship. The significance level (p-value) is 0.326 and therefore we cannot reject the null hypothesis of no correlation and suggest the data is inconclusive. The results suggest a weak negative correlation between the perceived level of digital tool adoption and perceived changes in minority patient accrual rates, but the effect is very small. There is a slight tendency for offices with higher clinical trials office digital adoption to have lower perceived increases in minority accrual rates. However, this relationship is not statistically significant at the conventional alpha level of 0.05 and suggests that the observed correlation as weak as it could be easily due to random chance. It is important to note that a p-value of 0.326 indicates there is weak evidence that the two variables correlate which could be accounted for by the sample size.

$$\textit{Minority Patient Accrual}_i = \beta_0 + \beta_1(\textit{Urban/City})_i + \beta_2(\textit{Suburban})_i + \beta_3(\textit{Other})_i + \beta_4(\textit{Digital Tool Adoption})_i + \beta_5(\textit{Academic medical center – Non designated})_i + \beta_6(\text{Freestanding cancer center})_i + \varepsilon_i$$

A linear regression was employed to investigate the relationship between digital tool adoption and minority patient accrual for trials at clinical trials offices. The model included the following independent variable: *digital tool adoption* (numerical) and the control variable for hospital location (categorical): Urban/City (binary), *Suburban* (binary), and *Other* (reference category); and institution type: *Academic medical center – National Cancer Institute (NCI) designated* (binary), *Freestanding cancer center* (binary), *Academic medical center - Non designated* (binary) and *Other* (reference category).

The model employed for H_2 explained a modest (10.3%) and non-significant proportion of the variance in minority patient accrual (F=1.440, p = 0.021). The coefficients table revealed no statistically significant individual variables at the alpha level of 0.05. For digital tool adoption, there was a trend towards a negative association with minority patient accrual (β = -0.097, p = .386). Institutions with higher digital tool adoption tended to have lower minority patient accrual, but this effect did not reach statistical significance. Regarding the location of the clinical trials office, compared to the reference category (*Other*), urban locations (β = .167, p = .210) showed trends towards having higher minority patient accrual while rural locations (β = - .021, p = .866) showed trends towards having lower minority patient accrual, although these effects were not statistically significant. Regarding the type of institution, the clinical trials office academic medical centers that were not non-designated (β = .108, p = .353) showed trends towards having higher minority patient accrual while freestanding cancer centers (β = - .194, p = .103) showed trends towards having lower minority patient accrual, although these effects were also not statistically significant. The model excluded the variables suburban and academic medical center – NCI designated due to multicollinearity (high correlation with other included variables). In Table 7 the model statistics are summarized in which eighty-two respondents were captured in the analysis with the utilization of listwise deletion in the analysis.

Table 7.
Regression Coefficients for Explaining Minority Patient Accruals

	B (SE)	β	ι	ρ
Digital Tool Adoption	-.061 (.070)	-.097	-.871	.386
Urban	.266 (.211)	.167	1.263	.210
Rural	-.070 (.412)	-.021	-.169	.866
Other	-.196 (.523)	-.048	-.376	.708
Academic medical center - Non designated	.162 (.173)	.108	.935	.353
Freestanding Cancer Center	-.572 (.346)	-.194	-1.652	.103
Constant	4.228 (.346)		10.532	<.001

Note: $R^2 = .103$ (N = 82, p = .211)

The hypothesis aimed to understand if digital tool adoption would correlate to minority patient accrual. Since the location of a clinical trials office could play to the accessibility of minority populations and the type of institution could play towards resource availability, these variables were evaluated to understand the relationship. While the model captured a modest, significant, portion of the variance, none of the individual variables reached statistical significance.

Study Limitations

The lack of significance in the models has the potential to stem from sample size, confounding factors not included in the model such as language barriers, cultural preferences, trial design, minority patient accruals and level of training, workflow disruptions, not distinguishing between voluntary versus involuntary (e.g. layoffs) staff exits for staff turnover as well as measurement limitations. One specific limitation is not further defining the response choices for the 7-point Likert scales for minority patient accrual and turnover, e.g., strongly decreased (more than 30%); moderately decreased (10 to 29%); slightly decreased (less than 10%) – some type of referent for all respondents to use. Other unmeasured factors that may play into the success of digital tools are hospital outreach programs, community engagement, or socioeconomic factors for minority patient accruals as well as workload, compensation, or work-life balance for staff turnover (Triningsih & Darma, 2023). Additionally, the reliance on self-reported data comes with its expected flaws, e.g., missing data (45% of respondents did not complete the survey) and respondents were not able to answer the question. Missing data could also partially be attributed to survey length and respondents not being able to answer an item.

Future studies could benefit from larger, more representative samples to reduce the influence of potential bias, objective measures of digital tool adoption, minority patient accrual, and staff turnover, rather than relying solely on perceptions, and exploring specific types of digital tools and their influence on work processes and staff experiences. Overall, this study provides a preliminary exploration of a complex issue. Future research with more rigorous designs can offer a clearer understanding of how digital transformation can optimize clinical trial operations and create a more positive work environment for research staff.

Managerial Implications

While the findings are inconclusive, they do highlight the need for further investigation into the potential impact of digital tools on clinical trial efficiency and staff satisfaction. With staff turnover rates presently as high as 30% (BDO, 2021), investing in digitalization to retrain staff is not just about adopting new technologies; it's about creating a more efficient, data-driven, and successful future for clinical research teams. By automating repetitive and administrative tasks, digital tools free up valuable time for research staff to focus on higher-value activities. Staff are engaged in more strategic and impactful work, driving productivity and better research outcomes. The demanding nature of clinical research roles often leads to burnout, but digital tools provide a means to mitigate this by automating mundane tasks and providing more flexible work options, such as remote monitoring and telemedicine visits. This flexibility enhances work-life balance and job satisfaction, reducing turnover rates (BDO, 2021).

Digitalization of clinical trials offices and the accrual of minority patients require more study into what drives the relationship. Research for the future should focus on identifying the precise mechanisms through which digital tools influence minority patient accrual. It is crucial to explore how these tools can be effectively utilized to overcome barriers to participation, such as lack of awareness, transportation difficulties (Abdulai, 2021), and mistrust of the healthcare system (Gray et al., 2021; Reopell et al., 2023).

Understanding the nuances of digital tool adoption and its impact on minority patient accrual is vital for improving the diversity and inclusivity of clinical trials. By addressing the specific needs and challenges of minority populations, we can ensure that clinical research reflects the diversity of the patient population and ultimately leads to better health outcomes and generalizable results.

Most importantly the findings highlight the importance of considering both digital tool adoption and institutional characteristics when addressing staff turnover and minority patient accrual in clinical trials. Managers should focus on enhancing digital tool adoption to reduce staff turnover while exploring additional strategies to improve minority patient participation. By understanding the unique challenges and opportunities associated with different institution types and locations, managers can develop tailored approaches to improve engagement, efficiency, and outcomes in clinical trials.

CHAPTER 3

STUDY 2A – DIGITAL MATURITY OF CLINICAL TRIALS OFFICES

Introduction

The digitalization of clinical trials offices is pivotal for the success of decentralized clinical trials. An aspect of decentralized clinical trials that is often overlooked as evidenced by the lack of literature on the topic presently available. The adoption of digital tools is the initial/implementation phase of digitalization for clinical trials offices in the journey to incorporating digital tools to streamline and facilitate operational support of their efforts of patient recruiting/screening, data entry, patient engagement efforts, etc. The impact of digitalization is only as successful as the implementation and integration of the tools into existing processes. This phase of incorporation of digital tools is referred to as the digital maturity of the organization. The concept of digital maturity is imbedded in the concept of the measurement of the value generation through digital aspects by an organization (Nasiri et al., 2022). Digital maturity is not obtained by adoption of digital tools by accident or achieved quickly. It does not simply mean adopting a new technology or digital tool to support strategies, staff, or structure. It entails adaptation of the tools and process (Kane et al., 2017). With this in mind the question was asked, *How does the digital maturity of the clinical trials offices that adopt digital tools impact the quality of the data and the study start-up process of clinical trials?*

This question was addressed through a quantitative method in which structure survey responses are analyzed to capture trends and patterns in data. A second part is executed in this research with the incorporation of the analysis of an open-ended question encouraging responders to add anything they might feel would help further gain insight into the perception of stakeholders on digitalization as a whole. These two methods provide an intriguing opportunity to compare the quantitative data with the qualitative results to further strength or explain the findings of this research.

Literature Review

Digital Maturity

Driven by the adoption of digital technologies, the healthcare industry is undergoing a significant transformation. While the adoption of digital technologies is driving the change, the digital maturity of the implementation is the key to the success of the change. Digital maturity is the extent to which an organization can effectively integrate digital technologies into its core operations and culture (Leso et al., 2023). This concept facilitates the measurement of the capability of an organization to leverage these technologies to achieve its strategic goals and provide value.

The concept of digital maturity encompasses various themes, i.e., integration (Krasuska et al., 2020), effectiveness (Johnston, 2017a), strategic alignment (Carvalho et al., 2019) culture (Flott et al., 2016a), etc. Integration entails the development of a cohesive digital ecosystem in which technology connects and supports aspects of the organization's workflows seamlessly (Blondiau et al., 2016). This is achieved by breaking data silos and ensuring cohesive exchange and conformity between systems such as electronic health records, clinical trials systems, and financial systems allowing for efficiency. Integrated process automation can help streamline workflows allowing for the ability to increase human resources for higher-value tasks and reduce error

(Kouroubali et al., 2019). Effectiveness is the ability to achieve measurable results with digital technologies. Data analytics can be utilized to optimize the allocation of resources, patient care improvement, and predict challenges (Johnston, 2017a). Data maturity pivots on utilizing data to refine processes and ensure positive changes which are achieved by monitoring key performance indicators such as completion rates, error rates, patient satisfaction, etc. (Grooten et al., 2018). Effectiveness is also gauged by the user-friendliness of interfaces and functionalities from the perspective of key stakeholders such as staff and patients (Bhati et al., 2023). Regarding strategic alignment, there is a need for a strategic vision of how digital technologies can drive an organization's ultimate goals and objectives (Martin et al., 2019; Van De Wetering et al., 2010). Another aspect of digital maturity is the need for a cultural shift towards one in which digital technology is embraced to foster success (Randall et al., 2019). Employee engagement is essential with appropriate training to facilitate comfort and literacy (Vidal Carvalho et al., 2019) in the digital tools being utilized. Effective change management strategies (Potter et al., 2018) are essential to minimize resistance by addressing employee concerns and encouraging adoption (Flott et al., 2016b). Open communication and facilitating collaboration across departments and units to leverage technologies to achieve common goals are crucial to maximizing the benefits of digitalization. Focusing on these themes can achieve digital maturity to reach the full potential of technology to create the ultimate goals of efficiency, innovation, and a patient-centric system of healthcare.

Data Quality In Clinical Trials

In 2021, the consulting firm Gartner reported that poor-quality data cost organizations an average of $12.9 million (Bansal, 2021). In literature, many definitions for data quality exist with many emphasizing the concepts of consistency, completeness, accuracy, and validity (Abdouli & Omri, 2021; Pipino et al., 2002). For the purpose of this paper, data quality will focus on the accuracy of data with emphasis on “fitness of use” (Richesson et al., 2013) with the data consumer in mind. Data quality in the healthcare industry can hold adverse effects on the continuity of care for patients, the safety of the patient, the productivity of the provider, and research integrity (Koepke et al., 2015; Makeleni & Cilliers, 2021; Wang et al., 2019).

The foundation of successful clinical trials is quality data. When data is inaccurate or incomplete, patient safety is jeopardized through inaccurate results regarding efficacy and safety of investigational treatments (Wang et al., 2019). Poor data quality can hide adverse events that can vary in their severity. The FDA and other regulatory agencies require high-quality data for approval of research drugs (Gibby, 1997). With poor-quality data, medical progress is hindered by delayed drug development or leads to the approval of harmful and ineffective treatments by misleading results (Holmes et al., 2021). Poor data quality can ultimately lead to a significant waste of resources in the form of money, time, and personnel through the amount of effort spent on collecting and management of the data.

Study Start-Up Timelines

A significant undertaking both logistically and administratively, the study startup phase at a research site entails the tasks of the development of a protocol through to the opening of a clinical trial at a research site. This phase involved both a study activation and a study set-up process. The tasks include but are not limited to assessing the feasibility of a study for a research site, the development of a budget and contract, various internal reviews such as scientific reviews and regulatory reviews, and developing the pieces needed to successfully operationalize the site at the research site. This process, depending on how cohesive the tasks align, can take over six months with the greater time taken showing and increased likelihood and a study never reaching its threshold due to inadequate enrollment in the trial (Ratnayake et al., 2024). In 2020, the National Institute of Health (NIH) reported that about eighty percent of trials do not reach their targeted enrollment goals or initial timelines leading to delays that resulted in about $8 million dollars of lost revenue per day of delay for companies that developed the drugs (Brøgger-Mikkelsen et al., 2020). Furthermore, delays in study start-up timelines affect the ability to be able to provide potentially lifesaving or life-improving treatments for patients with more chronic or life-threatening illnesses that often do not often have the luxury of time (Lai et al., 2021; McSpiritt, 2017).

For clinical trial offices, many factors can play in the delay of startup. These factors are heavily dependent on trained research professionals along with partnerships with various stakeholders, i.e., professionals who deal with budgets, contracts, lab processes, hospital facilities, commercial vendors, etc. (Clinvigilant, 2023; Dorwart, 2024). Digitalization of clinical trials offices offers the ability to leverage technology to allow for automation of submission processes and management of tasks throughout the study start-up process.

With this in mind, this research was executed with the aim of gaining a better understanding of where clinical trials offices stand in the second phase of digitalization, i.e., the digital maturity journey. This research assessed the digital maturity of the clinical trials offices that have adopted digital tools. Particularly the impact of digital maturity on the operational processes of the clinical trials office was explored. Survey results from a structured survey were analyzed for trends. The focus was on digitalization within clinical trials offices on operational efficiencies, i.e. quality of data entry and the effects on study start-up timelines. This provided further insight into the impact of the maturity of the digitalization efforts of the clinical trials offices that responded to the survey.

Conceptual Framework And Hypothesis

The digital landscape of clinical research is rapidly evolving. While adopting new technologies is a crucial step, the true measure of success lies not simply in implementation or adoption, but in the impact these digital technologies have on outcomes. This dissertation explores the concept of digital maturity and its critical role in optimizing the effectiveness of clinical trials offices.

Digital maturity goes beyond the simple adoption of technology. It reflects an organization's ability to strategically leverage digital solutions to drive meaningful operational results. In 2023, Deloitte released the report for the Digital Maturity Index Survey. The study suggested that many organizations that moved beyond the basics of digital adoption had accelerated progress in comparison to less mature companies (Deloitte, 2023). This further highlighted the importance of digital maturity to achieve further benefits with the adoption of digital tools or organizational digitalization.

For the purpose of this research, digital maturity is defined as the ability of an organization to adapt and apply its digital technology effectively as a byproduct of alignment of both internal and external people, culture, structure, and tasks to take advantage of opportunities enabled by the digital technology framework (Johnston, 2017b; NHS England, 2023; Snowdon et al., 2024). This research categorizes the digital maturity spectrum within the context of clinical trials offices from an iteration of the four stages of digitalization that was featured on Forbes Magazine's website (Grossman, 2018). Four distinct levels are defined to capture digital maturity with the impact on data quality and study start-up timelines explored.

Data Quality

Digital maturity enables clinical trials offices to implement advanced data management systems and automation tools that significantly reduce human errors in data entry, leading to higher data quality and reliability (Abdouli & Omri, 2021). This integration ensures that data is captured accurately and consistently, which is essential for the integrity of clinical trials and the validity of the outcomes (Pipino et al., 2002). By leveraging digital technologies, clinical trials offices can streamline data entry processes, minimize manual interventions, and enhance the overall efficiency of clinical trials.

Moreover, the strategic vision of a digitally mature clinical trials office fosters a culture of continuous improvement and innovation. By promoting the adoption of best practices in data management and encouraging the use of cutting-edge technologies, clinical trials offices can drive significant improvements in data entry quality. For example, the integration of artificial intelligence (AI) and machine learning (ML) algorithms can automate data validation processes, ensuring that errors are detected and corrected as soon as they are discovered. This enhances data accuracy and reduces the time and resources spent on manual data correction, thereby improving overall productivity in clinical trials. The alignment of digital technologies with organizational processes allows clinical trials offices to capitalize on opportunities enabled by the digital technology framework.

The leadership and management skills of the leaders of the clinical trials office are critical in the level of digital maturity that is implemented. Effective leadership involves not only the implementation of technology but also the training and development of staff to ensure they are proficient in using these tools. Clinical trials office leaders who prioritize digital literacy and provide ongoing training programs can empower employees to utilize technology effectively. Furthermore, by fostering a collaborative environment where feedback and continuous learning are encouraged, the clinical trials office can ensure that data entry processes are continually refined and improved. This alignment of people, culture, and tasks with digital technologies is essential for maintaining high data quality standards.

The impact of a digitally mature clinical trials office on data entry quality can be seen in the overall performance of clinical trials. High-quality data is essential for accurate reporting which would lead to the development of new therapies. Robust and reliable data entry processes can enhance an organization's ability to conduct not merely efficient but effective clinical trials. This holistic approach improves data entry quality and contributes not just to the advancement of medical research but to the timely delivery of innovative treatments to patients. This led to the first hypothesis tested:

HYPOTHESIS 1 (H_1): *The digital maturity of the clinical trials office is associated with improvement in data entry quality.*

Study Start-Up Timelines

Through the rise of digital technologies from electronic data capture (EDC) and clinical trial management systems (CTMS) to cloud-based collaboration platforms and artificial intelligence-driven analytics, digital tools are increasingly being integrated into and rapidly transforming various stages of the clinical trial lifecycle. This evolution of technology in clinical trials presents both opportunities and challenges for clinical trial offices, which are tasked with efficiently and effectively managing the complex processes involved. While the adoption of individual digital tools often improves specific aspects of clinical trial operations, the true potential of digital transformation lies in incorporating aspects of digital maturity. This concept encompasses the strategic alignment of people, processes, and technology to maximize the value derived from digital technology investments. As clinical trials offices navigate digital shifts in processes and tasks, understanding the impact of a process in the execution of tools through digital maturity on key performance indicators, such as study start-up timelines, is crucial.

The concept of digital maturity encompasses a holistic view that places emphasis on organizational capabilities and strategic alignment. Incorporating digital technologies alone is not sufficient to drive meaningful change. Organizational factors, such as leadership commitment, organizational culture, and employee skills, as well as consideration of the impact on existing technologies and processes, play a pivotal role in successfully leveraging digital technologies. This perspective emphasizes the need for a holistic approach to digital technology incorporation of a clinical trials office, one that integrates technology with people, processes, and strategy. This integration is crucial for achieving a state where the clinical trials office can effectively adapt and apply digital technologies to achieve its strategic objectives.

Study start-up timelines represent a critical bottleneck in the clinical trial process. Increased timelines have cascading effects, impacting overall study conduct timelines which could delay the delivery of new treatments to patients and cost clinical trial sponsors millions in losses. Numerous factors contribute to prolonged start-up timelines, including but not limited to, regulatory submissions, and contract and budget negotiations. Digital technologies offer the potential to streamline and accelerate traditional manual processes, though how effective they are depends on the level of digital maturity in implementing the technologies. Clinical trials offices that show digital maturity in implementation are better positioned to leverage digital tools to automate tasks, improve communication and collaboration, and enhance data management, all of which can contribute to a reduction in study start-up timelines.

By aligning people, culture, structure, and tasks with its digital framework, a digitally mature clinical trials office can create a synergistic effect where the incorporation of the digital tool or process can enhance and add to what is already in place. A clinical trials office that has trained its staff on how to effectively use a clinical trials management system and integrated it with other systems is more likely to see improvements in study tracking and management. A clinical trials office that embraces data-driven decision-making and fosters collaboration among stakeholders can further amplify the benefits of digital technologies it incorporates into the overall office and healthcare system. The alignment of all factors, i.e. internal and external, is crucial for tangible improvements in operational efficiency and reduced timelines. This led to the second hypothesis tested:

HYPOTHESIS 2 (H_2): *The digital maturity of the clinical trials office is associated with reduction in study start-up timelines.*

The independent variable digital maturity was utilized with the dependent variables of (H_1) data quality and (H_2) study-start-up timelines. A control was incorporated into the model to account for the potential effect of a clinical trials office budget on the model. Figure 5 depicts the conceptual model being proposed.

By examining the digital maturity of clinical trials offices, we aim to understand how effectively they utilize technology to enhance efficiency in clinical trial operations, improve data management and quality, and reduce costs associated with trials by reducing study start-up timelines which in turn would accelerate recruitment and retention of study participants and ultimately, bring life-saving treatments to patients faster.

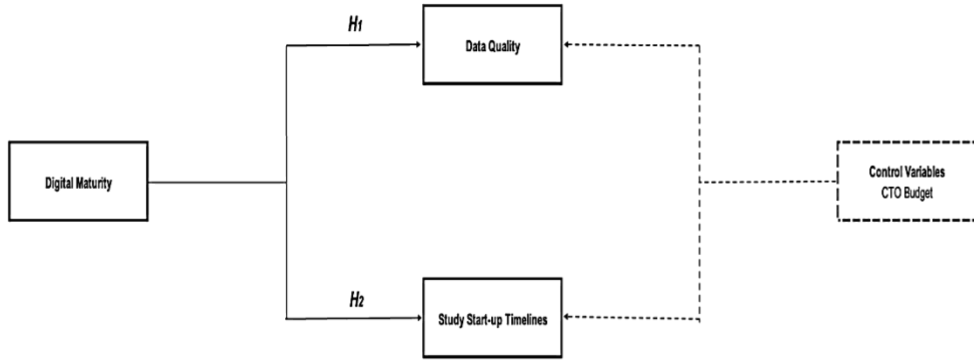

Figure 5. Conceptual Model for Digital Maturity in Clinical Trials Offices.

This dissertation explored the current state of digital maturity in clinical trials offices, identifying key factors influencing their digital transformation journey, and proposing actionable strategies for achieving a higher level of maturity. By leveraging the power of digital solutions, clinical trials offices can play a pivotal role in streamlining clinical research, accelerating medical progress, and ultimately, improving patient outcomes.

Research Method

The research adopted a quantitative and qualitative approach to understand the impact of the digitalized maturity of clinical trials offices for two key operational metrics of the clinical trials office – data quality and study-start-up timelines. This mixed methodological approach allowed for the examination of both measurable outcomes. Structured surveys were employed that allowed for a systemic approach for data collection and standardized responses that could be quantified as well as an open-ended question that could be analyzed for trends and insight. The goal was to provide an avenue for statically analyzable data as well as some unstructured data that would not be possible with one method. Structured surveys also allow for pattern assessment, observing trends in data and associations across diverse groups of respondents.

Survey Design

The survey developed for study one was utilized for study two. The survey was generated using Qualtrics software (Provo, Utah) and included about twenty-five questions that asked about sites, the impact of digital tools regarding patients as well as the office and its budget. The survey addressed cancer center demographics, level and tools incorporated for digitalization of the clinical trials office, study portfolios of the office, estimate office budgets and staffing/operational trends as well as patient trends since the implementation of digital tools in the clinical trials office.

Data Collection

The survey was sent to the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) listserv which comprised of eighty-two academic and National Cancer Institute (NCI) designated cancer centers in North America at the time of the survey. The listserv serves as a resource available to clinical trials office staff to discuss best practices, solutions, and challenges that sites might be facing. The survey was sent out to the listserv on March 20, 2024, and ran through July 1, 2024. The participation rate for the survey was 25% with 160 respondents.

Measures

The independent variable *Digital Maturity* was captured with a question in regard to the level of digitalization adopted by the clinical trials office. The options were adapted from four stages that were developed by Justin Grossman for Forbes, i.e., *incidental, intentional, integrated, and optimized* (Grossman, 2018). Incidental was defined as clinical trials offices with limited engagement, and accidental digital initiatives lacking a strategic vision. Intentional was defined as clinical trials offices demonstrating a purposeful approach to digital transformation, but efforts are still siloed and lack automation. Integrated was defined as clinical trials offices with successful implementation of multiple digital initiatives with clear strategic intent, resulting in demonstrable business impact, and optimized was characterized by a seamless integration of technology into existing systems, processes, and organizational culture.

For the H_1 dependent variable *Data Quality*, respondents were asked what was observed since the implementation of digital tools with seven answer options ranging from strongly decreased to strongly increased. Data Quality was defined as the accuracy of clinical trial data. For the H_2 dependent variable *Study Start-up Timelines,* respondents were asked the extent to which digitalization had impacted the timelines for study startup with seven answer options ranging from strongly decreased to strongly increased. Study Start-up was defined as from study selection/conception to open-to-enrollment status. In

Table 8 the operational variables are explained with questions asked and answer options included.

Table 8.
Variable Operationalization (Study 2A)

Variable	Question	Options
Digital Maturity	What level of digitalization has your Clinical Trials Office/Research Office adopted?	Incidental (reactive adoption) - engage in digital initiatives sporadically and without a clear plan or strategy. These efforts are often reactive and driven by individual initiatives rather than a cohesive organizational approach. Intentional (for specific processes) - digital initiatives are focused on specific areas or processes of the CTO. Integrated (embedded into CTO operations - have successfully embedded digital strategies into operations. Digital processes are streamlined and embedded into day-today work. Optimized (cornerstone of operations) - have fully embraced digital transformation, making it an integral part of culture and operations. Leverage digital tools and strategies to optimize clinical trial processes, enhance patient engagement, and accelerate research progress.
Data Quality	As best you can, please rate the extent to which digitalization has impacted clinical trial operations conducted with regard to the following: Quality (accuracy) of clinical trial data:	1=Strongly decreased; 2=Moderately decreased; 3=Slightly decreased; 4=Not changed; 5=Slightly increased; 6=Moderately increased; 7=Strongly increased
Study Start-up Timelines	As best you can, please rate the extent to which digitalization has impacted clinical trial operations conducted with regard to the following: Study Start-up Timelines (i.e., from study selection/conception to open to enrollment status)	1=Strongly decreased; 2=Moderately decreased; 3=Slightly decreased; 4=Not changed; 5=Slightly increased; 6=Moderately increased; 7=Strongly increased
CTO Budget	Please estimate to the best of your knowledge, the annual budget of the clinical trials office is.	less than $1,000,000; $1,000,000 to $2,000,000; $2,000,001 to $3.000,000; $3,000,001 to $4,000,000; $4,000,001 to $5,000,000; $5,000,001 to $6,000,000; $6,000,001 to $7,000,000; $7,000,001 to $8,000,000; $8,000,001 to $9,000,000; $9,000,001 to $10,000,000

Data Analyses

The dependent variables of *data quality* and *study start-up timeline* were tested for normality. The correlations between *digital maturity* with *data quality* and *study start-up timeline* will be estimated utilizing the appropriate correlation. A regression model will be employed to further evaluate the relationship between *digital maturity* and *data quality* and *study start-up timeline* respectively. Analyses were performed using SPSS statistical software, version 28 (IBM Corp., Armonk, NY).

Results

Listwise deletion was implemented for all the analyses conducted in this study and subsequently, the number of respondents shows variation with various analyses conducted on the data. For analysis of the respondents for the study, eighty-nine respondents were captured for demographics based on the dependent and independent variables being tested. Forty-six (51.6%) of these respondents were administrators, which was defined as senior-level management responsible for overseeing the overall operations, finances, and strategic direction of the clinical trials office. Twenty-four (27%) were research managers or supervisors while the remaining respondents consisted of seven (7.9%) research coordinators/data specialists, one associate director/medical director, and eleven (12.4%) respondents who did not fit the categories list, and were classified as *Other* which respondents reported as roles that included of regulatory specialist/coordinator, chief research officer, research compliance officer, clinical trials management system coordinator, director of clinical research informatics, etc. Twenty-five (28.2%) of the respondents reported being tenured at their respective clinical trials office between five to ten years while twenty-three (25.8%) were tenured for two to five years, nineteen (21.8%) were tenured for ten to fifteen years and eighteen (20.2%) were tenured for more than fifteen years. The respondents represented sixty-three (70.8%) National Cancer Institute (NCI) designated academic centers, twenty-two (24.7%) non-NCI academic centers, and four (4.5%) freestanding cancer centers that were solely dedicated to cancer research and care. In Table 9, the characteristics of survey respondents are summarized.

Variable Testing

The descriptive statistics for the independent variable "Digital Maturity" revealed that most respondents (47.2%) had felt that their clinical trials offices had "integrated" as the level of digitalization that was adopted. The term integrated was defined as having successfully embedded digital strategies into operations, i.e. digital processes were streamlined and embedded into day-to-day work. 38.2% of respondents had reported that they felt that their clinical trials office had been intentional, or digital initiatives were focused on specific areas or processes of the clinical trials office.

The descriptive statistics for the dependent variable "Data Quality" revealed that most respondents (20.6%) felt that the data quality of clinical trials office staff slightly increased (15 – 29%) with the digital maturity of the clinical trials office. 16.3% of respondents reported that data quality moderately increased, while 10.6% observed no change in data quality.

Table 9.
Characteristics of Survey Respondents (Study 2A)

Characteristic	Response	N (%)
CTO Role	Associate Director/Medical Director	1 (1.1)
	Administrator	46 (52.3)
	Research Manager/Supervisor	24 (27.3)
	Research Coordinator/Data Specialist	7 (7.9)
	Other	10 (11.4)
Years of Tenure at CTO	6 months - 1 year	2 (2.2)
	1 - 2 years	2 (2.2)
	2 - 5 years	23 (25.8)
	5 - 10 years	25 (28.1)
	10 - 15 years	19 (21.3)
	> 15 years	18 (20.2)
Institution	Academic – NCI-designated	22 (24.7)
	Academic non-NCI designated	63 (70.8)
	Freestanding Cancer Center	4 (4.5)

N = 89; listwise deletion utilized for DV and IV combined

The descriptive statistics for the variable "Study Start-up Timeline" revealed that the majority of respondents (18.8%) felt that study start-up timelines did not change with the digital maturity of the clinical trials office. 12.5 % of respondents reported a slight decrease in timelines while 10.6% reported a slight increase. In Table 10, a summary of all the statistics of all the variables is summarized with all variables assumed to be of normal distribution.

Table 10.
Variable Summary Statistics (Study 2A)

		Digital Maturity	Data Quality	Study Start-up Timelines
MEAN (SD)		2.49 (.739)	5.02 (1.168)	4.06 (1.283)
MEDIAN		3.00	5.00	4.00
SKEWNESS (SE)		-.189 (.241)	-.746 (.255)	.200 (.255)
KURTOSIS (SE)		-.279 (.478)	.724 (.506)	-.219 (.506)
Kolmogorov-Smirnov	Statistic	.284	.223	.185
	df	89	89	89
	Sig.	<.001	<.001	<.001
Shapiro-Wilk	Statistic	.832	.890	.943
	df	89	89	89
	Sig.	<.001	<.001	<.001

Hypothesis Testing

The normality of the variables of *data quality* and *study start-up timelines* was assessed using the Kolmogorov-Smirnov (K-S) test and the Shapiro-Wilk (S-W) test. The K-S and S-W for the variables of *data quality and study start-up timeline* (p <.001) were significant for both K-S and S-W but considering the skewness and kurtosis were less than one, a normal distribution is presumed despite the K-S and S-W results. Pearson's correlation was utilized for both variables to test the hypotheses. In Table 11, the correlation statistics are summarized which utilize listwise deletion in the analysis therefore capturing eighty-nine respondents for the analyses.

Table 11.
Correlation Statistics (Study 2A)

Pearson's Correlation		**Digital Maturity**
Data Quality (N=89)	Correlation Coefficient	.435
	Sig. (2-tailed)	<.001
Study Start-up Timelines (N=89)	Correlation Coefficient	.139
	Sig. (2-tailed)	.193

H_1: The digital maturity of the clinical trials office is associated with improvement in data entry quality.

The correlation coefficient between the variables of *digital maturity* and *data quality* is 0.435, indicating a direct relationship. The significance level (p-value) is 0.001

which is less than the threshold of 0.05, so we reject the null hypothesis of no correlation. The results suggest a positive correlation between the perceived level of digital maturity and the quality of data entered by staff in the clinical trials office. There is a tendency for offices with a higher level of digital maturity to have higher data quality, which is statistically significant and suggests that there is less than a .1% chance this correlation was observed at random.

$$Data\ Quality_i = \beta_0 + \beta_1(Digital\ Maturity)_i + \varepsilon_i$$

A linear regression was employed to investigate the relationship between digital maturity and data quality of staff at clinical trials offices. The model included the independent variable of *Digital Maturity* (numerical) and the dependent variable of *Data Quality* (ordinal).

The model employed for H_1 explained a modest (19%), significant proportion of the variance in data quality ($F = 20.35$, $p = <.001$). The coefficients table revealed no statistically significant individual variables at the alpha level of 0.05. There was a trend towards a positive association between digital maturity and data quality ($\beta = .688$, $p = <.001$). Institutions with higher digital maturity tended to have higher data quality, which was statistically significant. In Table 12, the model statistics are summarized in which eight-six respondents were captured utilizing listwise deletion for the analysis.

Table 12.
Regression Coefficients For Explaining Data Quality (Model 1)

	B (SE)	β	ι	ρ
Digital Maturity	.688 (.152)	.435	4.51	<.001

Note: $R^2 = .190$ (N = 89, p = <.001)

$$Data\ Quality_i = \beta_0 + \beta_1\ (CTO\ Budget)_i + \beta_2(Digital\ Maturity)_i + \varepsilon_i$$

A second linear regression was employed to investigate the relationship between digital maturity and data quality of staff at the clinical trials offices. The model included the following independent variable: *Digital Tool Maturity*(numerical) and the control variable for *CTO Budget* (numerical).

The model employed explained a modest (29.5%), significant proportion of the variance in data quality ($F = 5.872$, $p = .007$). There was a trend towards a positive association between digital maturity and data quality ($\beta = .598$, $p = .003$). Institutions with higher digital maturity tended to have higher data quality, which was statistically significant. In Table 13, the model statistics are summarized in which thirty-one respondents were captured utilizing listwise regression for the analysis.

Table 13.
Regression Coefficients for Explaining Data Quality (Model 2)

	B (SE)	β	ι	ρ
Digital Maturity	.598 (.181)	.528	3.31	.003
CTO Budget	.055 (.047)	.187	1.17	.251

Note: $R^2 = .295$ ($N = 31$, $p = .007$)

The hypothesis aimed to understand if digital tool maturity would correlate to data quality. Since the budget of the clinical trials office could play into the planning as well as what digital tools could be considered, this variable was evaluated to understand the relationship. Both models suggest that the variables, i.e. *Digital Maturity* and *CTO*

Budget, have a moderate and statistically significant relationship with *Data Quality*. Based on the moderate R^2 values (.19 and .295 respectively) and the significance values that are less than 0.05, *Digital Maturity* and *CTO Budget* appear to be a strong variable of *Data Quality*.

H_2: The digital maturity of the clinical trials is associated with reduction in study start-up timelines.

The correlation coefficient between the variables of *digital maturity* and *study start-up timelines* is .139 indicating a direct relationship. The significance level (p-value) is 0.193 and therefore we cannot reject the null hypothesis of no correlation and suggest the data is inconclusive. The results suggest a weak positive correlation between the perceived level of digital maturity and perceived changes in study start-up timelines, but the effect is very small. There is a slight tendency for offices with higher clinical trials office digital maturity to have higher perceived increases in increases in study start-up timelines. However, this relationship is not statistically significant at the conventional alpha level of 0.05 and suggests that the observed correlation as weak as it could be easily due to random chance. It is important to note that a p-value of 0.193 indicates there is weak evidence that the two variables correlate which could be accounted for by the sample size.

$$\textit{Study Start-up Timelines}_i = \beta_0 + \beta_1(\textit{Digital Maturity})_i + \varepsilon_i$$

A linear regression was employed to investigate the relationship between digital maturity and study start-up timelines for trials at clinical trials offices. The model included the independent variable of *digital maturity* (numerical) and the dependent variable of *study start-up timelines* (ordinal).

The model employed for H_2 explained a low (1.9%) and non-significant proportion of the variance in study start-up timelines (F=1.72, p = .193). The coefficients table revealed no statistically significant individual variables at the alpha level of 0.05. For digital maturity, there was a trend toward a positive association with study start-up timelines (β = .139, p = .193). Institutions with higher digital maturity tended to have higher study start-up timelines, but this effect did not reach statistical significance. In Table 14 the model statistics are summarized in which eight-two respondents were captured in the analysis utilizing a listwise regression for the analysis.

Table 14.
Regression Coefficients for Explaining Study Start-Up Timelines (Model 1)

	B (SE)	β	ι	ρ
Digital Maturity	.241 (.184)	.139	1.311	.193

Note: $R^2 = .019$ (N = 89, p = .193)

$$\textit{Study Start-up Timelines}_i = \beta_0 + \beta_1(\textit{CTO Budget})_i + \beta_2(\textit{Digital Tool Maturity})_i + \varepsilon_i$$

A second linear regression was employed to investigate the relationship between digital maturity and study start-up timelines for trials at clinical trials offices. The model included the following independent variable: *Digital Tool Maturity*(numerical) and the control variable for *CTO Budget* (numerical). The model employed for H_2 explained a very low (.6 %) and non-significant proportion of the variance in study start-up timelines (F=.085, p = .919). The coefficients table revealed no statistically significant individual variables at the alpha level of 0.05. For digital maturity, there was a trend towards a weak positive association with study start-up timelines (β = .069, p = .720). Institutions with higher digital maturity tended to have higher study start-up timelines, but this effect did not reach statistical significance. In Table 15 the model statistics are summarized in which eight-two respondents were captured in the analysis utilizing listwise regression.

Table 15.
Regression Coefficients for Explaining Study Start-Up Timelines (Model 2)

	B (SE)	β	ι	ρ
Digital Maturity	.101 (.278)	.069	.362	.720
CTO Budget	.017 (.072)	.044	.230	.820

Note: R^2 = .006 (N = 31, p = .919)

Both models suggest that the variables, i.e. *Digital Maturity* and *CTO Budget,* have a weak and not statistically significant relationship with *Study Start-up Timelines*. Based on the very low R^2 values (.019 and .006 respectively) and the significance values that are greater than 0.05, suggesting that neither *Digital Maturity* nor *CTO Budget* appear to strongly explain *Study Start-up Timeline*s.

Study Limitations

While data quality was seen to show a significant positive impact from digitalization, study start-up timelines resulted in a lack of significance in the model. Study start-up timelines findings have the potential to stem from the sample size, and confounding factors not included in the model such as stakeholder barriers, clinical trials office infrastructures, trial design, etc. Missing data could also partially be attributed to survey length and respondents not being able to answer an item.

It is evident from the results that study-start-up timelines rely on more than digital tools. This process requires the alignment of many stakeholders, i.e. sponsors, study teams, contracts/legal, budgets, etc. to be successfully executed (Clinvigilant, 2023; Dorwart, 2024). While not easy to capture the human elements quantitatively, exploring feedback from staff on perceived hold-ups in the process and the role digital technologies play in this process would be helpful insight. Furthermore, insight into whether teams had dedicated staff to this process and whether these staff members were involved in the decisions and execution of these tools would be helpful.

Managerial Implications

The digitalization of clinical trials offices is a multifaceted process with varied impacts. The positive correlation between digital maturity and data quality underscores the importance of investing in digital infrastructure. Clinical trials offices with higher levels of digital maturity tend to have better data quality, which suggests that health care stakeholders should prioritize digital technology initiatives to enhance data quality through thoughtful planning and execution. Findings suggest a need to delve into the specific effects of individual tools and their interactions within the complex ecosystem of a clinical trials office since the diversity in the structure and operation of clinical trial centers poses a challenge for digitalization efforts. This highlighted the importance of selecting the right tools, involving relevant stakeholders in the decision-making process, and ensuring proper implementation and ongoing management.

Furthermore, the role of the resources of the clinical trials office, particularly the budget, is emphasized in these findings. While no effect was seen with study-start-up timelines, the fact that the effect was substantial for data quality, emphasizes the driver of money in this process. This finding can help clinical trials office leaders make stronger cases for the need to allocate larger budgets for digitalization efforts. These efforts can be investments in resources as well as tools for the proper planning and implementation of these tools.

CHAPTER 4

STUDY 2B – DIGITALIZATION OF CLINICAL TRIALS OFFICES

Introduction

With the context of the impact of digital adoption on staff and patient accruals along with the findings of the role of digital maturity for the operational process of study-start-up timelines and quality of data entered by staff, the question of how digitalization impacts the clinical trials offices that operationalize clinical trials at hospital/clinical sites could further be evaluated.

Research Method

To understand the effects of digitalization in both implementation and adoption, an open-ended question from the survey was analyzed. This qualitative approach allows one to delve deeply into the meaning, context, and individual perspectives of the respondents. By focusing on these aspects, we can gain a comprehensive understanding of complex experiences (Lim, 2024). This method enables the researcher to gather detailed information about people's feelings and thoughts, providing a richer understanding than quantitative data alone (Bhangu et al., 2023).

The findings from this analysis offer a way to see the world from an individual's perspective, giving us a holistic view of their experiences. It acknowledges that people's experiences, beliefs, and values shape their perception of reality (Neubauer et al., 2019). By considering these subjective perspectives, one can explore and gain valuable insights into the lived experiences of participants. This approach helps us appreciate the nuances of their experiences and understand the broader implications of digitalization in their lives.

Furthermore, this qualitative method highlights the importance of understanding the personal and contextual factors that influence how digitalization is perceived and adopted. By capturing these detailed insights, we can better address the challenges and opportunities associated with digital transformation. This understanding can inform more effective strategies for implementing and promoting digital technologies, ultimately leading to more successful outcomes.

Data Collection

A survey was generated using Qualtrics software (Provo, Utah) and included about twenty-five questions that asked about sites, the impact of digital tools regarding patients as well as the office and its budget. The survey addressed cancer center demographics, level and tools incorporated for digitalization of the clinical trials office, study portfolios of the office, estimate office budgets and staffing/operational trends as well as patient trends since the implementation of digital tools in the clinical trials office. An opportunity for feedback was given to respondents of the survey with the question, *Are there any additional comments you would like to share regarding digitalization of clinical trials and its impact?* The responses to this question were pulled into an excel file and analyzed for any underlying themes or insight.

Ten respondents provided feedback that was analyzed for common themes using excel that captured the responses. The respondents consisted of six leaders of clinical trials offices or direct managers of those that lead clinical trials offices and two research managers along with one education coordinator and a regulatory specialist. Most represented academic medical centers that were NCI-designated while one represented a non-NCI-designated academic center, and another one represented a freestanding cancer center that was solely dedicated to cancer research and care. The tenure of respondents varied with four respondents being at their respective clinical trials offices for over fifteen years, three being at the office between two to five years, and two respondents each being at their respective clinical trials offices for five to ten years and ten to fifteen years respectively. Table 16 summarizes the characteristics of the respondents.

Response Analysis

This qualitative analysis delves into the open-ended responses from a survey exploring the digitalization of clinical trials, specifically focusing on the prompt: "Are there any additional comments you would like to share regarding the digitalization of clinical trials and its impact?" The responses, though concise, provide valuable qualitative data that complement quantitative findings, offering insights into the lived experiences and perceptions of those working in this evolving field. The methodology employed a thematic analysis, a systematic approach involving the identification of recurring patterns and ideas, followed by the development of codes to represent these themes. This allowed for a structured and nuanced interpretation of the data, revealing key insights that extend beyond the numerical results.

Table 16.
Characteristics Of Respondents (Study 2B)

Characteristic	Response	N (%)
CTO Role	Administrator	3 (30)
	Regulatory Specialist	2 (20)
	Research Manager/Supervisor	1 (10)
	Associate Director of Administration	1 (10)
	Chief Research Officer	1 (10)
	Education Coordinator	1 (10)
	Chief Compliance Officer	1 (10)
Years of Tenure at CTO	2 - 5 years	2 (20)
	5 - 10 years	2 (20)
	10 - 15 years	2 (20)
	> 15 years	4 (40)
Institution	Academic – NCI-designated	7 (70)
	Academic non-NCI designated	2 (20)
	Freestanding Cancer Center	1 (10)

N = 10

Four overarching themes emerged from the analysis, revealing the complex landscape of digitalization in clinical trials. Firstly, *tool-specific impact and complexity* was a prominent theme, with respondents emphasizing the nuanced effects of individual digital tools. As one respondent stated, "Each tool has a different impact on clinical trial efficiency, data integrity, etc." This perspective highlights the challenge of assessing the overall impact of digitalization, as it necessitates a granular understanding of how various tools contribute to different aspects of clinical trials. This suggests that future research should consider the specific effects of individual tools and their interactions within the broader clinical trial ecosystem. Secondly, the theme of *implementation and user experience* was consistently identified as critical factors for successful digitalization. Respondents emphasized the importance of strategic planning, proper tool selection, user training, and system integration. As expressed by one participant, "although digitalization can be beneficial, it will only work when the right tools are selected, and the right people are included in the discussion, implementation, and management of said tools." Furthermore, the need for consistent user adoption and effective training was underscored, with respondents noting that "staff needs to utilize the features of the systems and do so correctly and consistently before a difference will be seen." This highlights the significance of considering the human element in digital transformation.

Thirdly, the *value and burden assessment* theme captured respondents' perceptions of the benefits and drawbacks of digital tools. Concerns regarding the return on investment (ROI) and the additional burden of implementation were frequently mentioned. "These tools involve additional burden, and we have not seen ROI yet but are hopeful," one respondent noted. This sentiment was coupled with the observation that "Digitalization to date has focused on business uses like study start-up and research billing," suggesting a potential imbalance in the application of digital tools across different areas of clinical trials. This theme emphasizes the need for careful evaluation of the cost-effectiveness and efficiency gains of digital tools, as well as a strategic approach to their implementation. Finally, the theme of *contextual variability and evolving nature* acknowledged the diversity of clinical trial settings and the dynamic evolution of digitalization. Respondents noted the mixed experiences with digital tools, stating that "some things are improved, others are dissatisfiers to staff and patients," and recognized the "Incredible diversity in the way centers are structured and operationalized." This theme underscored the need for flexibility and adaptability in digitalization strategies, as well as a recognition of the diverse contexts in which clinical trials are conducted.

The thematic analysis revealed that while respondents recognize the potential benefits of digitalization, they also highlight the importance of careful planning, user engagement, and a realistic assessment of value and burden. The findings suggest that a holistic approach, considering both technical and human factors, is essential for successful digital transformation in clinical trials. Furthermore, the analysis underscores the need for ongoing evaluation and adaptation to the evolving landscape of digital technologies and the diverse contexts in which clinical trials are conducted. The insights gleaned from these open-ended responses provide a valuable qualitative dimension to the study, enriching the understanding of digitalization's impact on clinical trial offices.

Table 17.
Themes on Digitalization of Clinical Trials Offices

Theme	Description	Comments
Tool-Specific Impact and Complexity	highlights that each digital tool has unique effects and that digitalization's impact is not uniform.	"Each tool has a different impact on clinical trial efficiency, data integrity, etc." "It is hard to answer some of the questions trying to think of the overall impact."
Implementation and User Experience	focuses on the practical aspects of tool implementation, including user adoption, training, and system integration	"although digitalization can be beneficial, it will only work when the right tools are selected and the right people are included in the discussion, implementation, and management of said tools" "Would have more improvements but staff need to utilize the features of the systems, and do so correctly and consistently, before a difference will be seen." "It would be helpful to have integration between the EMR and the CTMS." "we are using a central digital training system for new staff for core trainings and surveys"
Value and Burden Assessment	captures the respondents' perceptions of the value and burdens associated with digital tools, including ROI concerns	"These tools involve additional burden and we have not seen ROI yet but are hopeful" "Digitalization to date has focused on business uses like study start-up and research billing."
Contextual Variability and Evolving Nature	acknowledges the diversity of clinical trial settings and the ongoing evolution of digitalization.	"Definitely evolving and expanding." "some things are improved, others are dissatisfiers to staff and patients." "Incredible diversity in the way centers are structured and operationalized."

Study Limitations

This qualitative analysis, while providing valuable insights, is subject to certain limitations. The data is derived from a small sample of open-ended responses, which may not be representative of the broader population of individuals involved in clinical trial digitalization. The conciseness of the responses, while insightful, also limits the depth of understanding that could be achieved through more extensive interviews or focus groups. Furthermore, the analysis is based on self-reported perceptions, which may be influenced by individual biases or interpretations. The lack of specific contextual information about the respondents' roles, institutions, or the specific digital tools they are referencing further constrains the generalizability of the findings.

The thematic analysis, while rigorous, is inherently subjective. The interpretation of themes and the coding of responses are influenced by the researcher's perspective, which may introduce potential biases. While efforts were made to ensure consistency and transparency in the coding process, alternative interpretations of the data are possible. The survey design itself, as noted by one respondent, may have introduced limitations by making assumptions about the structure and operation of clinical trial centers, potentially influencing the responses and limiting the scope of the data collected.

Managerial Implications

The findings of this analysis have several managerial implications for clinical trial offices. The quantitative finding of the earlier studies (Table 18) revealed that while there was a decrease in staff turnover and an increase in data quality with digital adoption and maturity respectively, there was a decrease in minority patient accruals and increase in study start-up timelines. This plays into the responses around implementation and user experience. Clinical trials offices should adopt a strategic and holistic approach to digitalization, focusing not only on the technical aspects but also on the organizational and human factors. This involves careful selection of tools, robust implementation plans, and ongoing management processes. Clinical trials offices should prioritize user training and support, recognizing that successful digitalization hinges on staff utilizing digital systems effectively. This may involve developing comprehensive training programs, providing ongoing technical support, and addressing potential resistance to change.

Table 18.
Summary of Hypotheses Testing Results

Hypothesis	**β**	**ρ (0.05)**	**Testing**
H_1: The adoption of digital tools for clinical trials is associated with a reduction in the turnover of research teams.	-.249	.022	Supported
H_2: The adoption of digital tools for clinical trials is associated with improvement in the accrual of minority patients on clinical trials.	.061	.386	Not supported
H_1: The digital maturity of the CTO is associated with improvement in data entry quality.	.528	.003	Supported
H_2: The digital maturity of the CTO is associated with a reduction in study start-up timelines.	.069	.720	Not supported

Clinical trials offices should evaluate the cost-effectiveness and efficiency gains of digital tools, focusing on demonstrating clear ROI and mitigating the implementation burden. This requires a data-driven approach, monitoring the impact of digital tools and adjusting as needed. Furthermore, clinical trials offices should address system integration challenges, particularly between EMR and CTMS, to enhance interoperability and streamline workflows. Finally, clinical trials offices should recognize the diverse contexts in which clinical trials are conducted and adopt flexible and adaptable digitalization strategies. This involves fostering a culture of continuous improvement, monitoring the evolving landscape of digital technologies, and tailoring strategies to meet the specific needs of their institution.

CHAPTER 5

DISCUSSION AND CONCLUSION

The first study aimed to explore the relationship between the perceived adoption of digital tools in clinical trial offices and key outcomes: changes in staff turnover and minority patient accrual rates. The second study aimed to explore the perspective of clinical trials teams in the implementation of digitalization of their respective offices with the key outcomes of data quality and study start-up timelines. The findings suggest some interesting trends, but limitations restrict the ability to draw definitive conclusions.

Discussion

For leaders in clinical trial organizations, embracing digital transformation is no longer a choice but a strategic imperative for survival and success. To view digitalization merely as a route to immediate efficiency is to fundamentally misunderstand its transformative power. Digital tools are the foundation upon which we will build a more resilient, adaptable, and ultimately, more impactful clinical research environment. This isn't just about doing things faster; it's about fundamentally rethinking *how* we operate, innovate, and deliver better patient outcomes and ensure research equity. As leaders, one must cultivate a culture of continuous improvement and innovation, ensuring our teams are not just equipped for today's challenges, but are future proof for the evolving landscape of modern clinical research. Investing in digitalization is an investment in our workforce, empowering them with the skills and tools to thrive in an increasingly digital world and guaranteeing our organizations remain competitive, innovative, and at the forefront of medical advancement and social responsibility.

This research compels leaders to confront critical questions about the very infrastructure of clinical trial offices. For hospital executives, research operations leaders, industry collaborators, and stakeholders across the field, the digitalization of clinical trials is not confined to oncology but is equally vital, perhaps even more so, in complex arenas like device trials. However, even as we strive for digital excellence, we are confronted with two intertwined crises: staff turnover and a persistent lack of diversity in patient accrual. As highlighted across diverse industries and specifically within clinical research, staff retention is not just an HR concern; it is a critical operational vulnerability. With staff turnover rates reaching as high as 30% (BDO, 2021), the need for strategic action is undeniable. When experienced professionals depart, they take with them invaluable institutional knowledge and expertise, crippling operational efficiency and jeopardizing the very advancements we seek to achieve. Furthermore, the persistent underrepresentation of minority patients in clinical trials undermines the generalizability and ethical validity of our research, hindering our ability to deliver equitable healthcare solutions for all populations.

Patient care continuity is fractured, patient safety is placed at risk during onboarding, and the delicate trust that fuels patient accrual and retention is eroded by staff turnover. This turnover doesn't just impact morale; it fundamentally undermines the patient experience, fostering mistrust at the very heart of the patient-researcher relationship. Furthermore, and with profound implications for research integrity, staff turnover increases the risk of data entry errors and compliance breaches, threatening the validity of entire clinical trials. Compounding this, the under-representation of minority patients in clinical trials perpetuates health disparities and limits the applicability of research findings to diverse populations.

As leaders, there is a call to challenge assumptions and broaden perspective. Are clinical trials offices truly leveraging the potential of digitalization if the operational foundations are weakened by preventable staff turnover and if research fails to reflect the diversity of the patients served? It is time to move beyond incremental improvements and embrace a paradigm shift. This research serves as a call to action, demanding a fundamental rethinking of the approach to clinical trial operations, staff well-being, and patient inclusivity. To effectively navigate this complex and multifaceted transformation, and to ensure sustained success, there is a need to embrace a series of key managerial implications, acknowledging that both digital tool adoption as well as institutional characteristics are critical factors. While some findings remain areas for further investigation, the direction is clear: digital transformation, strategically implemented, offers a powerful pathway to a more efficient, equitable, and impactful future for clinical research.

A key takeaway is to adopt a strategic and holistic approach to digitalization. This is not merely about adopting new technology; it demands a strategic overhaul of clinical trial offices. Leaders must move beyond a purely technical focus and recognize that digitalization is fundamentally about transforming an organization and empowering staff. Organizations need to be careful with tool selection and invest in purpose-built digital solutions that truly align with the organization's specific needs, workflows, and strategic goals. Recognition of the complex ecosystem within one’s clinical trial office is needed and an understanding of the specific effects of individual tools and their interactions.

Another takeaway is the need for a robust implementation plan recognizing that digitalization is not a plug-and-play solution. Successful implementation requires meticulously planned and phased rollouts, consideration of change management principles, and anticipating potential disruptions. Pilot programs, iterative testing, and clear communication are essential. Additionally, ongoing management processes as essential since digital tools are not static. They require continuous monitoring, maintenance, and optimization. Clear processes for system updates, data security, performance monitoring, and user feedback loops to ensure long-term effectiveness as essential.

Prioritizing user training and support empowers and retains clinical trial staff. The most advanced digital system is useless if staff cannot effectively utilize it. User training and support are a top priority and the cornerstone of successful digitalization and staff retention. With staff turnover rates at alarming levels, digitalization must be viewed as a key strategy for both retraining *and retaining* valuable staff. Streamlined workflows and enhanced interoperability are another key component of the success of tools with isolated digital systems creating data silos and hindering efficiency.

The digital landscape is constantly evolving, and clinical trial centers themselves are diverse in structure and operation. Clinical trial offices must therefore be agile and adaptable, ready to embrace new technologies and tailor their strategies to their unique context, and to the specific needs of diverse patient populations. This requires fostering a Culture of Continuous Improvement and Encouraging a mindset of continuous learning, experimentation, and adaptation within an organization. Regularly review processes, evaluate new technologies, and be open to evolving digital strategy. Recognition that there is no one-size-fits-all digital solution and adapting an organization's digitalization strategy to the unique context, resources, and needs of an institution are crucial for achieving optimal outcomes and ensuring equitable access to and representation in clinical research.

This research provides a clear and compelling roadmap for leaders seeking to navigate the complexities of digital transformation in clinical trial offices. By embracing these managerial implications – adopting a holistic strategy, prioritizing user empowerment and staff well-being, demonstrating return on investment (especially in data quality and efficiency), ensuring system integration, fostering adaptability, and actively addressing diversity and inclusion – leaders can not only future-proof their organizations but also drive significant improvements in patient outcomes, research integrity, staff satisfaction, and the overall advancement of medicine and health equity. The positive correlation between digital maturity and data quality provides a compelling financial and ethical justification for these investments, and the imperative to enhance diversity and inclusion adds a crucial dimension to this leadership challenge. The future of clinical trials depends on courageous leadership that is willing to rethink assumptions and embrace a digital-first mindset, grounded in strategic planning, a deep commitment to the human element and staff well-being, a clear understanding of the diverse and multifaceted nature of this digital transformation, and an unwavering dedication to equity and inclusion in clinical research.

Conclusion

For clinical trials offices, embracing digital transformation is a strategic imperative. The benefits of digital tools extend beyond immediate efficiency gains; they pave the way for a more resilient, adaptable, and successful clinical research environment. By fostering a culture of continuous improvement and innovation, clinical trials offices can ensure that their teams are well-equipped to meet the demands of modern clinical research, ultimately leading to better patient outcomes and organizational success (Barton, 2022). Investing in digitalization prepares the workforce for future challenges and opportunities, equipping staff with the skills and tools needed to navigate an increasingly digital landscape and ensuring that the organization remains competitive and innovative.

This dissertation opens up opportunities for further conversations surrounding the impact of digitalization of clinical trials offices for hospital sites that would benefit hospital executives, research operations leadership, collaborators, and industry stakeholders for the execution and conduct of clinical trials not solely in the oncology space but in other more complicated clinical arenas such as device trials. Staff retention is an issue that plagues many industries (Hickman & Pietrocini, 2022, PricewaterhouseCoopers. (n.d.)., 2022) can impede the operations of clinical trial offices that play a central role in the advancement of medicine. Experienced staff take valuable institutional knowledge and expertise with them when they leave, hindering clinical trial operational efficiency. Patient care continuity is disrupted, and patient safety is at risk as new staff are being trained and onboarded. Patient accrual and retention are driven by the trust patients develop with clinical trial staff. Turnover can impact this relationship, leading to mistrust and a negative patient experience (Salvagioni et al., 2017). Turnover increases the risk of data entry compliance and integrity issues, potentially compromising the integrity of clinical trials (Bridgeman et al., 2018).

Healthcare management researchers benefit from the insight provided into a world that is not presently researched. Hospital sites are seen as service providers to pharmaceutical companies with a blind eye to the struggles that sometimes ensue with the introduction of digital tools and processes. Clinical trials need patients for trials. These patients come from clinical sites. These sites are operationalized by staff that run trials. This research provides insight into the need for organizations to invest in their service providers for their advancement. This research hopes to further guide discussions on the advantages of digitalization platforms for the further optimization of clinical research operations. Though this research was not able to find significant trends, understanding the administrative, high-level business implications of digitalization of clinical trials offices, enabling stakeholders to make informed decisions, and optimizing resource allocation can advance the adoption of decentralized trial models in various clinical research domains.

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APPENDIX

IMPACT OF DIGITALIZATION on CLINICAL TRIALS OFFICES SURVEY (STUDY 1 AND STUDY 2)

Introduction

The healthcare industry is undergoing a rapid transformation, driven by advancements in technology and a growing emphasis on data-driven decision-making. This digitalization trend has also impacted clinical trials, with many Clinical Trials Offices (CTO)/Research Offices (RO) adopting digital tools and processes to improve efficiency and enhance patient outcomes.

This survey aims to assess the impact of digitalization on CTOs/ROs by gathering insights into the demographics of the offices, the tools or processes they have implemented, and the perceived effects of these implementations on CTOs'/ROs' efficiency and clinical trial patients.

By participating in this survey, you will be contributing valuable data that will help us better understand the impact of digitalization on clinical trials and provide CTOs/ROs with the tools they need to make informed decisions about future digital initiatives.

The survey will take about fifteen minutes to complete. Please do your best to answer all items, estimate if necessary. There is also an option to come back and complete it later if you need to verify any information you provide.

Your participation is greatly appreciated.

Section 1: Profile

What is your role in the Clinical Trials Office (CTO)/Research Office (RO)?

1= Associate Director/Medical Director (Medical Leader)
2= Principal Investigator
3= Administrator (senior-level management responsible for overseeing the overall operations, finances and strategic direction of the CTO)
4= Research Manager/Supervisor
5= Research Coordinator/Data Specialist
6= Other (please specify)

Which of the following best describes the type of institution you represent?

1= Academic medical center - Non designated
2 = Academic medical center - National Cancer Institute (NCI) Designated
3= Freestanding cancer center dedicated solely to cancer research and care
4= Government laboratory or private research institute focused on cancer research
5= Hospital or clinic without a formal designation as a cancer center
6= Other (please specify)

How long have you been a part of the CTO/research office?

1= < 6 months
2= 6 mths - 1 year
3= 1 - 2 years
4= 2 - 5 years
5= 5 - 10 years
6= 10 - 15 years
7= > 15 years

Where is the CTO/RO located?

State:

Describe the location of your CTO/RO.

1= Urban/City
2= Suburban (outskirts of a city)
3= Rural
4= Other

Section 2: Digitalization Tools and Processes

To the best of your knowledge, to what extent has the Clinical Trials Office (CTO)/research office adopted digital tools or systems to enhance processes? (E.g.: eReg binders, eConsent platforms, wearable devices, screening tools, etc.)

1= No extent: no digital tools or systems adopted
2= Very minimally: There may be some initial exploration or pilot projects, but the overall adoption is limited.
3= Minimally: Some steps have been taken towards adopting digital tools or systems for clinical trial processes, but the implementation is limited in scope and impact.
4= Moderately: There are some initiatives in place, but there is room for further expansion and integration.
5= Significantly: There is a substantial investment in digital technologies, leading to noticeable improvements in efficiency and effectiveness.
6= Very significantly: There are transformative changes in clinical trial processes. The organization is a leader in leveraging digital technologies for enhancing trials.
7= Completely: Fully embraced. The organization has integrated digital technologies

seamlessly into its operations, leading to optimal efficiency and outcomes in clinical trials

What is the primary reason the CTO/research office has not adopted digital tools or systems?

1= Cost and Resource Concerns (Upfront Investment, Legacy Systems Integration)
2= Security and Privacy Issues (Data, Regulatory Compliance)
3= Workflow and Change Management (Resistance to Change, Expertise Limitations)
4= Technical Challenges (Data Integration, System Interoperability)
5= Limited Connectivity
6= Rapidly Evolving Technology
7= Other

Which of the following digital tools or processes are being used in the CTO/research office? (Select all that apply)

1= Electronic patient-reported outcomes (ePRO) systems
2= Electronic data capture (EDC) systems with remote data collection capabilities
3= Mobile health (mHealth) applications
4= Telemedicine platforms
5= Wearable devices
6= Cloud-based clinical trial management systems (CTMS)
7= Robotic process automation (RPA) tools for automating such as data entry, scheduling, and reporting
8= Electronic Regulatory Binder
9= Patient Screening/Matching Tools (AI-based)
10= eConsent
11= Virtual reality (VR) and augmented reality (AR) tools to enhance patient education, training, and therapy, improving understanding and adherence to study protocols.
12= EHR to EDC systems
13= Automated Research Radiological Reads
14= Other (please specify)

To the best of your knowledge, how long has the CTO/Research Office been using digital tools or processes?

1= Less than 1 year
2= 1 - 2 years
3= 2 - 5 years
4= 5 - 8 years
5= 8 - 12 years
6= 12 - 15 years
7= > 15 years

Based on your understanding, what is the primary source of funding for the tools/systems?

1= Institutional Support
2= Industry Support
3= Philanthropy
4= Other (please specify)

To the best of your knowledge, what were the primary goals for the adoption of digital tools or processes at the CTO/Research Office? (select all that apply)

1= Improve patient engagement and recruitment
2= Improve diversity of patient population on trials
3= Enhance data collection and management
4= Streamline clinical trial operations
5= Reduce administrative costs and regulatory burden
6= Improve the quality and integrity of clinical trial data
7= Other

What level of digitalization has your Clinical Trials Office/Research Office adopted?

- ○ **Incidental** (reactive adoption) - engage in digital initiatives sporadically and without a clear plan or strategy. These efforts are often reactive and driven by individual initiatives rather than a cohesive organizational approach
- ○ **Intentional** (for specific processes) - digital initiatives are focused on specific areas or processes of the CTO
- ○ **Integrated** (embedded into CTO operations) - have successfully embedded digital strategies into operations. Digital processes are streamlined and embedded into day-to-day work.
- ○ **Optimized** (cornerstone of operations) - have fully embraced digital transformation, making it an integral part of culture and operations. Leverage digital tools and strategies to optimize clinical trial processes, enhance patient engagement, and accelerate research progress.

Section 3: Patient Profile CTOs - non-digitalized

Please answer the following in regard to the present profile of the patients on clinical trials in the following aspects:

Minority Patients Clinical Trial Accrual

(Minority patients are defined as those that identified as Black or African American, Hispanic, and Asian)

To the best of your knowledge, over the last 2 years, the accrual of minority patients on clinical trials has: (Accrual = signed consent and started treatment)

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

To the best of your knowledge, over the last 2 years, the retention of minority patients on clinical trials has: (Retention - remaining/completing trial)

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Patient Engagement (defined as compliance of patients with study procedures)
Over the last 2 years, as best you can estimate, patient engagement has:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Patient Accruals (i.e., patient has signed consent and started treatment)
Over the last 2 years, as best you can estimate, patient accruals have:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Patient Retention (defined as patient completing clinical trial)
Please estimate, as best you can, the change in patient retention over the last two years.

1= Significantly decreased
2= Moderately decreased
3= Slightly decreased
4= Not Changes
5= Slightly Increased
6= Moderately Increased
7= Significantly Increased

CTO Staffing - non digitalized
As best you can, please answer the following in regards to the present state of the Clinical Trials Office (CTO)/Research Office (RO) in the following aspects:

Employee retention (how long employees remain) over the last two years has:
1= Significantly decreased
2= Moderately decreased
3= Slightly decreased
4= Not Changes
5= Slightly Increased
6= Moderately Increased
7= Significantly Increased

Staff turnover (how many employees leaving) of the CTO over the last two years has:
1= Significantly decreased
2= Moderately decreased
3= Slightly decreased
4= Not Changes
5= Slightly Increased
6= Moderately Increased
7= Significantly Increased

Section 4: CTO

Which of the following choices best captures the size in terms of full-time equivalents (FTEs) for clinical trials office?

1= less than 25
2= 25 to 49
3= 50 to 100
4= 101 to 150
5= 151 to 200
6= 201 to 250
7= 251 to 300
8= 301 to 350

9= > 350

Please estimate to the best of your knowledge, the annual budget of the clinical trials office is.

1= less than $1,000,000
2= $1,000,000 to $2,000,000
3= $2,000,001 to $3.000,000
4= $3,000,001 to $4,000,000
5= $4,000,001 to $5,000,000
6= $5,000,001 to $6,000,000
7= $6,000,001 to $7,000,000
8= $7,000,001 to $8,000,000
9= $8,000,001 to $9,000,000
10= $9,000,001 to $10,000,000
11= more than $10,000,000

To the best of your knowledge, what are the funding sources for the clinical trials/research office? (must add to 100%)

- ☐ Governmental (i.e., NCI CCSG grant, Federal Grants, etc.)
- ☐ Institutional
- ☐ Philanthropy
- ☐ Trials (i.e., Industry)
- ☐ Other
- ☐ Total

CTO Profile additional

As best you can, please estimate what the primary funding sources for clinical trials/protocols in the portfolio. (must add 100%)

- ☐ External Peer Reviewed
- ☐ Industry
- ☐ Institutional
- ☐ National (NCI NCTN, etc.)
- ☐ Other
- ☐ Total

Rank the following trial phases in order of prevalence in the clinical trials office portfolio (1 being the most prevalent).

1= Phase I
2= Phase II

3= Phase III
4= Phase IV

Open Ended

Are there any additional comments you would like to share regarding digitalization of clinical trials and its impact? (Write "None" if not)

Contact Info

Are you willing to be contacted in the future for questions in regards to the digitalization of clinical trials offices and decentralized clinical trials?
The interview would be conducted virtually and take roughly 20-25 minutes.
You will have the opportunity to win one of ten Amazon gift cards valued at $25 if you choose to participate.

0= No
1= Yes

Contact Information

Name

Email

Section 5: Impact of Digitalization - CTO Staffing

As best you can, please answer the following on the extent to which digitalization has impacted the staffing of the CTO/RO on the following:

Retention of clinical trials office/research staff
(Retention = how long employees remain)

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Turnover of clinical trials office/research staff
(Turnover = number of employees leaving)

1= Strongly decreased

2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Section 6: Extra CTO Digital Impact

As best you can, please rate the extent to which digitalization has impacted clinical trials operations conducted with regard to the following:

Quality (accuracy) of clinical trial data:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Integrity (consistency and reliability) of clinical trial data:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Study Start-up Timelines (i.e., from study selection/conception to open to enrollment status)

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Overall time to conduct clinical trials (i.e., from open to enrollment to closed to enrollment):

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Section 7: Impact of Digitalization - Clinical Trial Patients
To the best of your knowledge, please answer the following in regards to the extent to which digitalization has impacted the patient participation in clinical trials since implementation in the CTO/RO:

Minority Patients on Clinical Trials
(Minority patients are defined as those that identified as Black or African American, Hispanic, Asian, and other)
To the best of your knowledge, since the implementation of digital tools, minority patient accruals on clinical trials has:
(Patient Accrual = signed consent and started treatment)

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

To the best of your knowledge, since the implementation of digital tools, the retention of minority patients in clinical trials has:
(Retention = remaining/completing a clinical trial)

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Patient Engagement (defined as compliance of patients with study procedures)
To the best of your knowledge, since the implementation of digital tools, patient engagement for all patients has:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Patient Accrual (defined as patient signed consent and started treatment)
Since the implementation of digital tools, as best you can estimate, patient accruals for all patients have:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Patient Retention (defined as patient completing/remaining on clinical trial)
To the best of your knowledge, since the implementation of digital tools in the CTO/RO, patient retention for all patients has:

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

Section 8: CTO Admin Questions

Please enter the name of your institution (optional)

The cost of initiating and implementing digital tools for the CTO
To the best of your knowledge, what was the estimated overall cost of initiating and implementing digital tools?

1= less than $200, 000

2= $200,000 to $399,999

3= $400,000 to $599,999

4= $600, 000 to $799,999

5= $800,000 to $999,999

6= $1,000,000 or more

To the best of your knowledge, what percentage of the implementation costs were covered by internal funding:

0 10 20 30 40 50 60 70 80 90 100

What were the factors contributing to the overall implementation costs? (select all that apply)

1= Complexity of digital tools
2= Size of the clinical trials office portfolio
3= Need for additional staff or training
4= Integration with existing systems
5= Data Security and Privacy tools
6= Vendor Fees and services
7= Software licenses and hardware
8= Other

To the best of your knowledge, what has been the overall impact of digitalization on the cost of conducting clinical trials?

1= Strongly decreased
2= Moderately decreased
3= Slightly decreased
4= Not changed
5= Slightly increased
6= Moderately increased
7= Strongly increased

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