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Telehealth Utilization in Clinical Trials: Facilitators, Barriers, and Future Directions

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BY

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A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

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Abstract of Doctoral Project Presented to the
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Abstract

Purpose: Telehealth implementation in clinical trials is not as well developed as compared to telehealth utilization in other areas of medical care. The focus of this project will explore the factors that foster and hinder the effective use of telehealth in clinical trials and how these insights can inform future strategies and policies.

Method: The project synthesizes empirical research and theoretical literature on the integration of telehealth into clinical trial. The research utilizes an online survey via REDCap to gauge the level of acceptance, perceived effectiveness, and potential barriers to the implementation of telehealth in clinical research.

Results: The responses of 25 professional participants highlight the optimistic perspective on the contribution of telehealth to clinical research and acknowledge the obstacles and opportunities that arise from the integration of artificial intelligence. The results provide insights into the factors that foster and hinder telehealth implementation for future expansion.

Conclusion: The project supported the expanded use of telehealth in clinical research to improve participant accessibility, diversity and recruitment, cost reductions, an increase efficiency. The policy implications include standardizing state licensure requirements and consistency in Investigational Review Boards (IRBs). Future research is recommended with larger sample sizes across a larger national or international region.

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CHAPTER I INTRODUCTION

1.1 Background and Need

Telehealth utilization has widely increased across most healthcare sectors since 2020 (Stoumpos et al., 2023). There are multiple potential benefits of integrating telehealth into healthcare delivery. From the point of view of the patient, telehealth has the potential to make healthcare more accessible and inclusive. In addition to enhancing patient comfort and outcomes, this methodology can expand access to underserved populations. Telemedicine can further reduce costs related to infrastructure and travel for patients who live in rural and remote areas (Haleem et al., 2021). All these benefits can be applied to telemedicine in clinical research. The research for the present study focuses on the importance of the integration of telehealth into clinical research with the potential to overcome traditional barriers such as patient recruitment and retention.

1.2 Problem Statement

While telehealth has been utilized in medical settings, the evidence supporting its in clinical trials is limited. Integrating telehealth into clinical trials presents a promising opportunity to enhance efficiency, inclusivity, and patient engagement. However, the lack of established best practices and understanding of the potential benefits and challenges hinders widespread adoption. The project aims to identify and inform best practices for telehealth use in clinical trials, addressing barriers and optimizing its application to improve clinical research outcomes.

1.3 Research Objective and Design

This project will address the advantages of telehealth that can be incorporated into clinical trials and address the questions of what barriers or challenges need to be considered to expand telehealth in clinical trials. A survey was developed to target medical and clinical research professionals to capture perceptions on current and future use of telehealth in clinical research. This work will focus on the main objective of what areas foster and hinder the effective use of telehealth in clinical trials, and how these insights inform future strategies and policies to optimize its application in this context. The present

project was directed toward the specific components of telemedicine that will emerge as best practices that will improve clinical research.

The project was conducted in two parts. The first component included a comprehensive literature analysis to inform the development of a survey. This was done to ensure that the questions asked were based on the current level of knowledge and practice. The second component involved the survey itself, which consisted of collecting empirical data from healthcare and clinical research practitioners working in the field.

The integrated design of the project included a review and synthesis of both empirical research and theoretical literature. Examples include work from the period of approximately 2018-2023 published by the Centers for Disease Control; the National Library of Medicine; and the American Medical Association. The empirical research will evaluate the efficacy of telehealth in clinical trials, and the theoretical literature will address ethical or regulatory concerns in the use of telehealth in clinical trials. The research objective of the integrated review is to synthesize empirical research and theoretical literature on integrating telehealth into clinical trials, thereby informing best practices, and addressing barriers.

1.4 Population

The project targeted participants from various medical backgrounds to gauge acceptance, effectiveness, and barriers to telehealth in clinical research. The targeted medical backgrounds include medical doctors, osteopathic medicine doctors, physician assistants, nurse practitioners, social workers, registered practicing nurses, and other similar medical professional categories in the United States. The targeted population is anticipated to be a representation of the larger health care community engaged in clinical research.

1.5 Need for Telehealth in Clinical Trials

While there is a need for the integration of telehealth into clinical trials, there are challenges and potential waste to consider. For example, a research company estimates that 20% of drugs in clinical trial research are wasted (Oximio, 2023). The waste is often due to complex designs that cannot meet supply

needs. Other challenges to many types of clinical trials include recruiting and reaching patients, patient retention throughout the clinical process, safety challenges, prioritizing clinical research priorities, and the extended length required in some clinical processes (Institute of Medicine, 2010).

Representative samples have often failed to be recruited for traditional clinical trials. Only five percent of eligible candidates are estimated to participate in traditional trials. With such a low sample, the clinical trials often lack representation from minority groups and certain geographic areas. When the Food and Drug Administration (FDA) approved the use of decentralized clinical trials and telehealth, researchers projected that increased representative samples may be recruited (Goodson et al., 2022). Research is still needed to explore additional methods, such as telehealth, to improve the recruitment process and representative samples for clinical trials.

The COVID-19 pandemic created a multitude of challenges in clinical research. One result was the loss of over 1,100 clinical trials per month during the peak years of the pandemic (Dahne et al., 2023). The trials were stopped or delayed due to the traditional methodology that could not be administered well during the pandemic. However, Pfizer and others used the opportunity to shift clinical research trials to a telehealth and non-traditional model. While much research was stopped, vaccine research accelerated the use of telehealth and non-traditional methods (Dahne et al., 2023).

1.6 Potential Benefits of Remote Clinical Trials

Offering clinical trials remotely removes travel and time barriers to participation. This benefit allows researchers to include underrepresented populations in their analysis to strengthen the generalization of their results. Moreover, this service would likely improve the comfort and compliance level of participants. By reducing the need for physical infrastructure and costs related to patient travel, sponsors will have additional research funds for further studies (Aily et al., 2023). The support for use of telehealth is well supported for decentralized clinical trials that use digital technologies to improve patient recruitment and reduce no-shows, targeting rare disease populations, receiving treatment through trials without travel, and allowing for remote patient monitoring that improves collecting data and patient information in real-time (Faget, 2021).

From a sponsor perspective, telemedicine is also very appealing, as many studies suffer from poor patient compliance and retention rates. The Community Preventative Services Task Force documents the support for patient compliance using telehealth. The improved compliance issues include medicine adherence, regular clinical monitoring such as blood pressure checks, and improved dietary schedules if advised by telemedicine communication (CDC, 2020).

Within normal standards of care, which include providing required care while evaluating and reducing the risk of harm, telehealth has been shown to improve the effectiveness and efficiency of healthcare delivery (Webster et al., 2021). However, this application has yet to be thoroughly explored for its practical uses in advancing clinical research related to safety and effectiveness (Hasselfield, 2022). The pandemic allowed researchers and funders to explore a novel way of conducting clinical trials, creating a pressure point for regulations such as licensure and telehealth standards (Faget, 2021).

The adoption of telemedicine as a standard across the industry lags behind traditional medical telemedicine use, which indicates a need to address the advantages of its use in clinical trials. Multiple challenges must be addressed before fully integrating telehealth into clinical trial designs. These challenges include data security and privacy, regulatory concerns, and ensuring that telehealth technologies are accessible to all patients regardless of socioeconomic status or geographic location (Kruse et al., 2020).

Current research shows that telehealth utilization in clinical trials can improve patient access, increase diversity, and reduce costs (Wasti et al., 2022). The American Medical Association (AMA) reported that 85% of physicians would use some form of telemedicine by 2021, which is now confirmed by an AMA Survey that reports over 80% of physicians use some form of telehealth (American Medical Association, 2022). This research also found that over 60% of clinicians believe that the level of patient care and interaction is equal to or better than in-person, 40% reported reduced healthcare costs as a result of telemedicine, and approximately 60% will promote the use of telemedicine in additional areas, which may include clinical trials (American Medical Association, 2022).

CHAPTER II SCOPING LITERATURE REVIEW

2.1 Introduction

The literature review will explore the use of telehealth in healthcare and the benefits and challenges of expanding telehealth to clinical trials. Implementing telehealth and telemedicine technologies has fundamentally altered the nature of the healthcare system (Hollander & Carr, 2020). The COVID-19 pandemic is primarily responsible for a significant portion of the accelerated expansion and implementation of telehealth services, as providers and patients sought out ways to limit exposure to the virus and preserve protective equipment (Webster et al., 2021). Although telehealth is already being used in many facilities that provide standard care, its application and acceptance in clinical translational research prompts further investigation (Kadir, 2020).

The literature review provides information on the current state of telehealth utilization in clinical research with the intention of informing best practice guidelines for its full integration into clinical translational research. It is important to understand how telehealth is utilized in clinical research, including recruitment, enrollment, patient monitoring, virtual consultations, and data collection. The review will also explore the potential benefits and challenges of implementing telehealth in this context, such as improved access to participants and reduced costs for researchers and patients. Lastly, thoughts on the future direction of research on this topic will be discussed to shape the direction of healthcare delivery and advance medical knowledge by utilizing modern technology in clinical trials.

2.2 Utilization and Effectiveness of Telehealth

Telehealth is expanding in the United States (US), especially during the height of the COVID-19 pandemic, with providers that include Yale New Haven Health System seeing an increase from 316 telehealth visits in 2019 to over 500,000 in 2020 (Chiang & Herbst, 2022). The World Health Organization (WHO) reports similar results internationally in Europe and Central Asia (WHO, 2022). Additional research supports that there are similar benefits and barriers to the use of telemedicine in Europe and the US, as identified by the WHO European region. This research notes that telemedicine is well-established in Europe. Still, some regions need improved technology access for patients and

healthcare providers' infrastructure to meet the growing telehealth system (Saigí-Rubió et al., 2022). Additional research is needed to support the future growth of telehealth in health care and clinical trials internationally.

The current state of telehealth utilization is steady since the significant increase experienced in 2020 and early 2021, primarily due to the pandemic. According to a pulse survey conducted by the Office of Health Policy, the use of telemedicine decreased in 2022 and 2023 from 30.2% to an average of 22% of adults report using telehealth in 2023 as a regular part of their healthcare. The current level of telemedicine use remains higher than pre-pandemic usage. The lowest utilization of telemedicine was among uninsured patients at approximately 9%, younger adults between the ages 18 and 24 at approximately 17.6%, and people living in the Midwest at 18.7% utilization. The higher utilization percentage occurs with patients on Medicaid or Medicaid at 26.8 to 28.3%, individuals identifying as Black at 26.1 %, and individuals with an annual income of less than $25,000 at 26.4%. This project also noted a difference in video telehealth services versus audio-only services. Hispanic, Latino, and Asian patients represent an approximate 20% higher percentage of patients utilizing telehealth, specifically without video, as compared to White patients. It is unclear if this difference relates to preference, broadband and technology access, or other factors (Karimi et al., 2022).

Research has been conducted on the use of telemedicine in the area of mental health clinical assessment and treatment. Worldwide, approximately one in eight individuals experience a mental illness that includes anxiety, depression, and postpartum depression as the most prevalent (Sugarman & Busch, 2023). It has become increasingly important to diagnose and treat individuals through a variety of methods. This research analyzed the reliability and treatment effectiveness of mental health assessments between telemental services (video and audio) and in-person services. The results indicated that telehealth and in-person patients had similar assessment treatment results and overall clinical outcomes. It is important to note that some patients had an undetermined variability that may be attributed to individual

patient characteristics and needs. Additional research should explore these differences and the impact of hybrid in-person and telehealth services for mental health treatment (Sugarman & Busch, 2023).

Additional researchers note that the future of clinical research should be informed by the use of telehealth in medical settings and treatments. Clinical trials have most often been conducted in brick-and-mortar settings. In the last two years, decentralized clinical trials (DCTs) and virtual trials (VTs) have been embraced by pharmaceutical companies and medical providers to expand research (Morgan & Nigam, 2022).

The COVID-19 pandemic also opened the door for a decrease in the regulatory requirements/guidance related to the use of telehealth in clinical research including the use of digital health tools for informed consent, monitoring, and assessments. These steps propelled the use of decentralized clinical trials (DCTs) where elements of the clinical trial are conducted remotely whether at home or close to a patient's home. The expansion of home delivery of medications also has a role in the expansion of DCTs. Research on the use of DCTs for improving research for surgical and multidisciplinary trials in oncology demonstrates promising results (Adesoye et al., 2023).

The COVID-19 pandemic provided a critical call to action in expanding the use of remote clinical trials. Research on potential treatments for COVID-19 provides additional support for using telehealth platforms in translational clinical research. Using a mixed-method design researchers examined the use of niclosamide, as an oral medication to reduce antiviral levels. A telehealth component to the clinical trial design was utilized for all study visits, coordination of participant specimens (self-collected), and to monitor symptoms. A post-participation survey was utilized to determine participant's responses to the use of telehealth in research. The results indicated that 77% would participate in future remote and telehealth based clinical trials and 93% reported they were moderately to very comfortable using the telehealth approach and technology. This study concluded that telehealth in clinical research is effective for the research design components and provides a positive experience for participants (Daudelin et al., 2022).

This research indicates that telehealth is effective and safe in healthcare and clinical settings. However, telehealth is limited in clinical research trials. The adoption of similar practices in clinical research could offer similar benefits and improve key performance indicators related to clinical trials.

2.3 Telehealth for Clinical Care

The adoption of telehealth into clinical care has happened quickly; however, its integration into clinical research has faced many obstacles and barriers (Naito et al., 2021). Historically, much of the research has used questionnaires and surveys (Webster et al., 2021). These approaches have gathered data on telehealth usage, patient satisfaction, and the efficiency of using this technology (Rockwell & Gilroy, 2020). More research is needed to demonstrate the utilization of telehealth as a tool in research designs, recruitment, enrollment, consent, follow-up, monitoring, and data collection.

The incorporation of telehealth in clinical care and research has encountered barriers to include variations in state licensure, limited access to technology for some populations, and inconsistency in Investigational Review Boards (IRBs). Researchers have proposed recommendations to expedite the use of telehealth in clinical trials in North America. The recommendations include requesting IRBs to allow for hybrid studies that promote flexibility between in-person and remote visits without a lengthy protocol amendment process. It is recommended that the overall delivery of healthcare and clinical research through telehealth be incorporated as a long-term solution. This step may require infrastructure and support in the operational costs of expanding telehealth tools. It is also important for IRBs and healthcare organizations to incorporate community needs and patient input into the expanding the design models for telehealth (Naito et al., 2021).

2.4 Telehealth Technology as a Clinical Research Tool

The impact of telehealth in clinical research has been explored in the United States (US) and internationally with varying results. Case studies have been performed to provide detailed data on various telehealth implementations in medical research (Ohannessian et al., 2020). More recently, researchers have authored papers focusing on the complexities of implementing telehealth as a solution (Chiang &

Herbst, 2022). Some key barriers identified in the literature include medical licensure requirements, reaching disadvantaged populations, and inconsistencies in IRBs (Kadir, 2020).

The statistical approaches in prior research include descriptive and comparative analysis (Webster et al., 2021). Most commonly, t-tests, chi-squared tests and linear regression were used (Rockwell & Gilroy, 2020). More complex research has included randomized controlled trials (RCTs), systematic reviews, meta-analyses, and mixed method approaches to gather qualitative and quantitative data to understand telehealth's impact on clinical research better (Ohannessian et al., 2020). The use of mixed method approaches that combine individual quantitative and qualitative methods may provide more comprehensive results. However, the skill set of the researchers to pull the information from both sets of data is critical to the success of the process (Ohannessian et al., 2020).

2.5 Recruitment

Research exploring the use of telehealth behavioral health services to decrease nicotine vape usage in young adults showed promising results. The participants were recruited through social media and a smartphone app, along with incentives for abstinence of vaping substance tests were utilized in the testing group. Most participants in the testing group completed the study, and 55% maintained abstinence samples throughout the study compared to 8% of the control group. The study indicates promising use of behavioral health telemedicine in young adults (Palmer et al., 2022). The use of non-traditional recruitment methods and telehealth treatment methods demonstrates that recruitment and participation may increase in clinical trials.

2.6 Enrollment and Consent

Telehealth has demonstrated the ability to increase the enrollment of qualified participants in clinical trials. Studies using telehealth for recruitment and enrollment demonstrate that it is convenient, especially for populations with serious diseases or limited ability to travel to clinical sites (Faget, 2021).

In a study exploring potential COVID treatments using telehealth, the ease of informed consent was noted as one of the advantages. This study used a mixed-method approach that included survey

questions to medical professionals focused on the benefits and barriers of telehealth in clinical research (Daudelin et al., 2022).

2.7 Follow Up and Retention

The follow-up process and care for patients and participants are other areas of important focus for the expanded use of telemedicine. Eysenbach found that telemedicine follow-up care should be addressed for each individual participant. However, more participants in this research successfully participated in follow-up through telemedicine instead of in-person (Eysenbach, 2018). These results indicate that the convenience and reach of telehealth increased participation in the follow-up process and allowed researchers to gather more longitudinal data and research results.

Specific to telehealth with clinical research, several studies have demonstrated beneficial outcomes of incorporating components of telehealth into the research methodology. A study on smoking and chronic obstructive pulmonary disease (COPD) evaluated the use of telehealth intervention to address both smoking cessation and screening for COPD issues. The study evaluated the acceptance and feasibility of e-visits instead of lab visits for pulmonary function testing and smoking cessation treatment with 125 patients. The results demonstrated favorability for in-home assessment of disease risk (76.6% assigned to this group), and all smoking cessation participants (except for 24-hour quit attempts) preferred e-visits. This research supports telemedicine's dual and proactive use in diagnosing and preventing health issues (Dahne et al., 2022). The ability to provide longer-term follow-up using telehealth is a promising practice in clinical trials.

2.8 Data Collection

When considering potential next steps to examine best practices for telehealth use in research, large-scale, multi-site RCTs comparing telehealth to standard care in a clinical trial setting would provide more comprehensive data (Meghiref et al., 2022). An RCT could be designed and conducted with thousands of participants across the US to compare variables like adherence, dropout rates, and trial outcomes (Faget, 2021). The longitudinal data gathered from this study could be analyzed to identify

common themes, further identifying what barriers exist and what strategies currently facilitate telehealth usage in the clinical research industry (Rhon et al., 2022).

An additional barrier or consideration for the use of telehealth and virtual clinical trial components is the patients' medical condition. In cases of oncology research, especially with advanced imaging of tumors and chemotherapy, limited telehealth use should be considered. The sensitivity of the medical conditions may require in-person sessions for most research components, including follow-up Kadakia and Asaad (2021).

Some have noted that the informed consent process is one of the significant challenges in clinical research, especially in the area of recruitment and reaching a wide array of potential participants (Gunther & Kuter, 2018). Telemedicine in the form of tele-consent offers a convenient method to meet with potential participants, discuss the process, and obtain consent. This process should assist researchers in screening non-qualified participants quicker and without travel to clinical sites and provide a method to cast a wider geographical search for appropriate research participants.

The literature review has provided validation and explored challenges in using telehealth in clinical research. The review has directed the scope of the current study to further explore the use of telemedicine in clinical trials.

CHAPTER III METHODOLOGY

3.1 Research Design

The project offers an overview of telehealth use and perception in clinical research and contributes to developing standardized guidelines for best practices. The project will synthesize empirical research and theoretical literature on integrating telehealth into clinical trials. The integrated design will include the literature synthesis to provide an overview of telehealth in clinical trials focusing on benefits, challenges, and future directions. The design adheres to systematic methods in data collection and analysis to ensure the reliability and validity of the findings. Project data from participants will be collected using an online survey via REDCap (Research Electronic Data Capture) (Harris et al., 2019). The survey will focus on gathering information about general attitudes, perceived benefits, and potential challenges of using telehealth in clinical research. The research design utilizes an anonymous survey targeted to clinical and medical related professionals.

Online anonymous surveys have been shown to efficiently gather data across a broad range of demographics and provide valuable insights into research questions (Wasti et al., 2022). This methodology is advantageous in its simplicity and speed and does not require the same level of participant engagement as mixed-method approaches. This type of research also removes the need for institutional review board (IRB) approval or informed consent forms, given the anonymity and non-invasive nature of the data collection and the overall goal of quality improvement and program evaluation (Wasti et al., 2022).

Current research suggests that telehealth utilization in clinical trials can improve patient access, increase diversity, and reduce costs (Wasti et al., 2022). It is projected that specific components of telemedicine will emerge as best practices in clinical research. This survey will focus on areas to include recruitment, monitoring, treatment, and data collection.

3.2 Sample Selection

Professionals were asked to participate in this project based on their role and experience within healthcare research. They will include individuals in the United States from various medical backgrounds, such as physicians, nurses, clinical researchers, and healthcare administrators—ideally, those who have interacted with telehealth services or been involved in clinical research. Snowball sampling will be utilized to reach participants beyond the initial target sample. This nonprobability sampling format will be used to recruit participants from professional networks and contact groups.

3.3 Instrumentation

The online survey via REDCap will consist of questions designed to gauge the level of acceptance, perceived effectiveness, and potential barriers to the implementation of telehealth in clinical research. The survey will be divided into sections to three primary sections: 1) Demographics: Questions will include age, professional role, years of experience in the medical field, experience with telehealth, and experience in clinical research; 2) Perceptions of Telehealth in Clinical Research: Questions will focus on familiarity with telehealth in clinical research, the effectiveness of telehealth integration, potential benefits, areas of telehealth use, and anticipated challenges; and 3) Future Perspectives: Open-ended questions about additional support or resources needed for telehealth implementation and the expected evolution of telehealth in clinical research over the next five years. The survey instrument was developed based on a review of the literature, and evaluated for content, and clarity by experts in the field. The survey instrument is available in Appendix A.

3.4 Data Collection/Procedure

Project data were collected and managed using REDCap electronic data capture tools hosted at The Medical University of South Carolina (MUSC). REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (Harris et al., 2019).

The responses from the survey will be stored anonymously using REDCap and analyzed to identify trends and correlations. The survey distribution will launch to the selected sample of healthcare professionals and will be promoted through professional networks, medical forums, and social media platforms to increase the survey visibility and promote engagement. This data will provide insights into telehealth's current state and future potential in clinical research. This data will be cross-referenced with the demographic information and the responses on perceptions of telehealth.

3.5 Data Analysis

After collecting the data and research information, the project included an analysis and interpretation of the findings. The responses will be analyzed to identify trends, correlations, and insights into the current and future state of telehealth in clinical research. The analysis will determine the factors that foster and hinder telehealth implementation in clinical trials and could inform future research and practice recommendations.

The data from the survey results will be analyzed using descriptive statistics based on the REDcap data set. The data will be analyzed based on distributions from the participant responses and measures of central tendencies. The themes that emerge from free response questions will also be summarized to inform the overall survey results.

3.6 Protection of Human Subjects

This project was submitted to the MUSC review board through the Investigational Review Board Quality Improvement program evaluation self-certification tool. The project was determined to involve a quality improvement process and not subject to IRB approval based on the following factors: the project does not involved the use of an experimental drug or device; the project has not received federal funding; the project does not involve multiple sites; the intent is not based on systematic investigation; the results will not be published or distributed outside of the MUSC; and the project is intended to improve and evaluate a process within a program at MUSC. Given this review of the project along with the anonymous nature of the survey and the non-sensitive data being collected, this project does not require IRB approval

or participant consent forms. However, the survey included a statement ensuring participants of their anonymity and the voluntary nature of their participation in the present project.

The results of the anonymous online survey will offer a broad overview of the use and perception of the uses of telehealth in clinical research. This will contribute to understanding its role in future medical practices and developing standardized guidelines for best practices.

CHAPTER IV RESULTS

4.1 Results/Findings

From March 6th, 2024, to March 20th, 2024, a survey was conducted to investigate the incorporation of telehealth into clinical trials. The survey received 25 responses through a snowball sample method by utilizing LinkedIn for distribution and was further amplified through shared professional networks. Further, the survey link was directly shared via email to three targeted healthcare administrators with a request to share with their teams. Considering the nature of distribution, the survey's exact reach and response rate is uncertain. This approach demonstrates a broad, yet focused interaction with individuals from different sectors of the medical and research community.

To tackle this inquiry, the survey aimed to discover and educate on the most effective methods for utilizing telehealth in clinical trials. Additional questions were also included to gather data on potential obstacles and maximizing telehealth's application to enhance outcomes in clinical research. The questionnaire template can be found in Appendix A and response data can be found in the Appendix B.

Outlined below are the main discoveries derived from the survey responses, organized into different categories such as participants' backgrounds, their encounters with telehealth in clinical trials, perceived advantages, encountered challenges, and recommended best practices for successful telehealth integration. Theme’s that emerged from two free responses questions included in the survey were also explored.

Table 1: Demographic and Professional Profile of Survey Participants on Telehealth in Clinical Research

Variable	N	Percent	Mean	SD
Age	25		41.2	9.0
Professional Role				
MD	3	12		
DO	1	4		
PA	0	0		
NP	1	4		
SW	1	4		
RPN	0	0		
Other	19	76		
Years of Experience in the Medical/Research Field	25		12	5.5
Experience with Telehealth				
Yes	22	88		
No	3	12		
Experience in Clinical Research				
Yes	25	100		
How would you assess your proficiency in utilizing Telehealth technologies within clinical research settings?				
Novice	3	12		
Advanced Beginner	7	28		
Competent	7	28		
Proficient	4	16		
Expert	4	16		

Demographic Profile of Participants

The survey collected responses from 25 professionals in the medical and research field, with an average age of 41.2 years (SD = 9.0). Most respondents indicated their professional role as 'Other' (76%), encompassing a range of positions in the healthcare and research sectors. The nineteen responses to ‘Other’ professional roles included Project Manager (15.8%), PhD (10.5%), DHA (10.5%), Master of Science (10.5%), Clinical Research Coordinator (10.5%), Clinical Scientist (5.3%), Physical Therapy Assistant (5.3%), Speech Pathologist (5.3%), Regulatory Analyst (5.3%), Study Start-up Manager (5.3%), Clinical research Associate (5.3%), Director (5.3%), and Registered Nurse (5.3%). This was followed by Physician (MD/DO) (16%), Nurse Practitioner (NP), and Social Worker (SW) (4% each). Survey respondents brought with them a vast amount of experience, averaging 12 years (SD = 5.5) in the medical/research field. A significant number of participants (88%) indicated that they had prior exposure to telehealth. In addition, all participants (100%) mentioned their experience in clinical research.

When assessing respondents' proficiency in using telehealth technologies within clinical research settings, results showed a range of self-assessed expertise. The most represented levels were 'Advanced Beginner' and 'Competent', accounting for 28% each. This was followed by 'Proficient' and 'Expert', both at 16%, and 'Novice' at 12% as shown in Table 1.

Impact of Telehealth on Clinical Research

Survey participants were requested to consider their direct involvement and evaluate how telehealth can improve the efficiency and effectiveness of clinical research trials. Most respondents (60%) expressed that telehealth has the potential to significantly enhance research, while 28% were even more optimistic, considering the impact to be transformative. A small percentage (12%) believed the impact was moderate. It was also observed that no respondents selected 'Not at all' or 'Marginally' related to telehealth's ability to improve clinical research.

Important Advantages of Telehealth in Clinical Research

The survey participants highlighted the advantages of incorporating telehealth in clinical research. A significant majority (88%) acknowledged enhanced accessibility for patients. Sixty-eight percent of respondents emphasized the importance of cost reduction and improved participant diversity. Additionally, a large portion (84%) recognized the role of telehealth in boosting enrollment efforts. Furthermore, many respondents (72%) expressed that telehealth had a positive impact on equity in participation, while 52% also highlighted improved efficiency in data collection as an advantage. A mere 12% offered additional, unspecified advantages.

Frequency of Integrating Telehealth Technologies

Participants reported various levels of telehealth integration in their clinical research activities over the past three years. Recruitment activities commonly involved the use of telehealth, with many participants (56%) reporting utilizing these technologies sometimes or often and a portion (20%) consistently relying on them. Remote screening (36%) and informed consent (32%) processes were also commonly observed. The integration of wearables or other sensors for remote monitoring and compliance

was not as common, with a significant portion of individuals (54.2%) never or rarely using them in practice.

Major Obstacles and Hurdles

Technical issues were observed to be the most prevalent challenge, 76% of participants recognized this as an obstacle to incorporating telehealth into clinical research. Sixty-four percent of individuals expressed concern regarding regulatory compliance. Less than half of the respondents recognized additional obstacles including, patient privacy concerns (40%), Building patient-researcher rapport (32%), and ensuring data reliability and security (32%).

Challenges Faced by Patients and Participants

The survey revealed various obstacles faced by patients or participants when using telehealth. The most mentioned concerns were related to technology access and literacy, with 84% of respondents reporting this issue. Internet accessibility was also a significant concern (72%). Concerns about the needs of an aging population and cognitive limitations were reported by 44% and 40% of respondents, respectively. Some participants mentioned facing challenges due to language barriers (44%) and their geographical location (24%).

Potential Applications of AI in Clinical Trials and Telehealth

When questioned about the potential application of artificial intelligence (AI) in clinical trials and telehealth, respondents expressed a strong preference for automated reminders and non-human check-ins (68%). Additional potential applications involved utilizing AI to improve trial design and offer live monitoring (44% each), along with identifying study populations that are not adequately represented (32%). A smaller percentage of individuals recognized the possibilities of automated conversation or question responses (36%) and overcoming obstacles in data analysis (36%).

The survey also included two optional free-response questions requesting information on experiences with the successful implementation of telehealth in clinical research and future perspectives/insights on its use within the industry. Of the 25 survey participants, 18 (72%) provided

responses to the first free response question and 19 (76%) responded to the second. Analysis of the data revealed key themes and resources for telehealth integration in clinical research.

Table 2: Key Themes from Direct Involvement and Future Predications of Telehealth Utilization in Clinical Trials

Theme	Representative Quote(s)	Meaning
Technical Support and Accessibility	"Having an IT person who is available during participant encounters (evaluations, treatments, and other data collection appointments) is crucial for addressing and resolving inevitable technical problems."	Ensuring reliable IT support is critical for the effective management of technical issues in telehealth.
Training	"Training for clinical investigators, study coordinators, and other staff on telehealth platforms, regulatory requirements, and best practices for virtual interactions. MUST BE DOCUMENTED (SUPER CRITICAL)"	Comprehensive training for healthcare professionals is necessary to navigate telehealth platforms and adhere to regulatory standards.
Telehealth-Specific Software and Infrastructure	"Telehealth software specifically designed for clinical research workflows, ensuring compliance with HIPAA and other data security requirements."	The development of specialized telehealth software is essential for seamless integration into clinical research workflows and maintaining data security.
Regulatory Guidance	"I expect the FDA and other regulatory bodies to provide more comprehensive and streamlined guidance, leading to greater adoption and confidence in using telehealth for various trial procedures."	Clear and detailed regulatory guidelines are anticipated to encourage broader adoption and build confidence in telehealth applications.
Increased Access	"Increased access and participation for people who live rurally and/or in underserved areas."	Telehealth is expected to broaden the accessibility of clinical trials to populations in remote and underserved locations.
Hybrid Trial Models	"Hybrid models, where some visits are in-person and others remote, will likely become standard for many studies."	The blending of in-person and telehealth interactions in clinical trials is anticipated to become a standard approach.
AI and Technology	"Integration of wearable devices, home-based diagnostics, and AI-powered analysis tools will expand the types of data that can be reliably collected remotely."	Advances in technology, including AI, are set to enhance data collection and broaden the scope of telehealth in clinical research.

Expansion and Reach	"With increasing technology, I believe telehealth will become utilized more in order to increase enrollment in clinical trials by saving patients travel time for routine follow up visits."	Telehealth is expected to expand in scope, making clinical research more accessible and convenient for a broader range of participants.

Free Response Question 1: What specific support or resources have you found essential for the successful implementation of telehealth in clinical research? (Please detail based on your experience)

Theme: Technical Support and Accessibility

The implementation of competent technical support staff was highly emphasized theme mentioned by clinical research professionals. Participants mentioned that having an IT expert present in real-time to troubleshoot any issues during telehealth sessions is crucial for the smooth operation of telehealth initiatives in clinical trials. There appears to positive association between IT support to address inevitable technical challenges that arise during patient encounters and the successful implementation telehealth in clinical research.

Theme: Training

A strong demand for comprehensive training programs was another theme that emerged. Participants believe professionals from various backgrounds, including those involved in research, administration, and patient care, need to have a strong understanding of telehealth platforms to ensure successful implementation. Responses suggest that proper training is crucial for understanding the intricate world of telehealth, where having the right knowledge can greatly influence the effectiveness of remote patient engagement and adherence to regulatory standards.

Theme: Telehealth-Specific Software and Infrastructure

A theme concerning the advancement of telehealth in clinical is related to the use of software specifically designed for telehealth purposes. Survey respondents noted that infrastructure should be customized to fit clinical workflows, integrating with electronic data capture systems and eConsent

platforms. This finding suggest that targeted platforms could help make research processes more simplified and efficient starting from patient enrollment to data collection and final reporting.

Theme: Regulatory Guidance

The need for explicit guidance from regulatory bodies was a recurring topic. Respondents anticipate receiving more comprehensive guidance from agencies (e.g., the FDA), as this would enhance their trust and willingness to embrace telehealth in a wide range of trial procedures. This implies survey participants agree that regulatory clarity is crucial for fully harnessing the potential of telehealth in clinical research.

Theme: Increased Access

Telehealth has the potential to revolutionize participation in clinical research, making it more accessible to a wider population. Participants predict an increase in opportunities for individuals in rural and underserved areas, leading to a broader range of research involvement and increased diversity, equity, and inclusion (DEI). This expansion is anticipated to improve the quality and relevance of clinical research findings among a wider range of people so all communities can benefit from advancements in medicine.

Free Response Question 2: Based on your direct involvement, how do you anticipate the role of telehealth in clinical research evolving over the next five years? (Please share your insights and predictions)

Theme: Hybrid Trial Models

The future of clinical trials seems to be a combination of different approaches. There is a growing agreement that clinical research will involve a combination of remote and in-person components. Participants believe this blended model ensures a combination of accessibility and thoroughness, providing convenience for trail subjects while maintaining research integrity.

Theme: AI and Technology

The incorporation of AI into telehealth has garnered significant attention and, at times, raised concerns amongst participants. Those surveyed believe there is hope that AI will improve the capabilities of telehealth, but there is also concern about the possible biases that AI algorithms may introduce. A delicate equilibrium between technological progress and ethical concerns remains a top priority for the future implementation of AI platforms within clinical research.

Theme: Expansion and Reach

Participants agree that the future of telehealth use in clinical research is positioned for exponential growth. Largely due to advancements in technology and regulatory changes that were prompted by the COVID-19 pandemic. Based off the data collected, there is a strong dedication to utilizing telehealth to improve the effectiveness, accessibility, and patient focus of clinical trials.

CHAPTER V DISCUSSION

5.1 Discussion of Results

The use of telehealth in medical settings has been well documented. However, the evidence supporting the use of telehealth in clinical trials is limited. In the problem statement, this research set out to examine the integration of telehealth into clinical research in areas to include enhanced efficiency, inclusivity, and patient engagement. The lack of established best practices and understanding of the potential benefits and challenges hinders widespread adoption. The project provided results and themes to further identify and inform best practices in telehealth that will guide the expanded use of telehealth in clinical research and inform best practices.

The survey results supported the growing importance of telehealth in clinical research from an experienced sample group in the area of clinical trials and ongoing research. The range of positions within the healthcare sector represented in the sample provide support for the continued adoption and recognition of telehealth in the medical and research fields. A significant number of participants (88%) indicated that they had prior exposure to telehealth and all participants (100%) mentioned their experience in clinical research. The responses indicate a wide range of comfort and proficiency levels across participants when using telehealth for research purposes. The higher experience levels in clinical research combined with most having some level of experience in telehealth increases the validity of the results.

The results support several key advantages of expanding telehealth in clinical research. Furthermore, the majority of the participants (88% combined) agree that telehealth will greatly enhance or provide transformational enhancements to clinical research. The most significant advantage noted was increased accessibility for patients to participate in research. The importance of accessibility was followed closely by the advantages of increasing enrollment and promoting equity in participation in clinical research. These advantages are correlated to the high rating for telehealth in increasing accessibility. These benefits to using telehealth are also supported in the literature review for improving access to current and future research. Faget (2021) noted the convenience and accessibility to research for

populations with serious illness or limited ability to travel to sites. The AMA (2022) also reported that over 80% of physicians use or would use some form of telehealth to improve patient care and accessibility.

The survey results indicated that the respondents most commonly integrated telehealth into clinical research for recruitment activities followed by remote screening and informed consent. The literature review also noted that treatments using informed consent and remote monitoring were highly significant factors in the use of telehealth (Daudelin et al., 2022).

Respondents noted limited use of wearables and monitoring medical devices as examples of telehealth use, which is a consistent finding with the literature review. The CDC reported on a promising practice of the use of devices to monitor blood pressure and dietary schedules by the Community Preventative Services Task Force using telehealth. The project demonstrated improved compliance with the addition of the use of devices (CDC, 2020). There seems to be an opportunity to further enhance clinical research as medical monitoring devices can be further integrated as a mainstream process.

This survey respondents indicated that technical issues and regulatory compliance are the primary obstacles for researchers in using telehealth. The respondents ranked technology access and literacy as the primary obstacles for participants in telehealth for clinical research. While these concerns were also common in the literature review, there was a significantly high percentage (84%) of participants in this project who rated the technology access for participants as a barrier. This higher result could relate to rural pockets in the project participation reach or unique experiences of the sampled population.

The themes that emerged from the open-ended questions in the project point to best practices to be incorporated into telehealth in clinical research. These themes support the primary research focus on the areas that foster and hinder the effective use of telehealth in clinical trials, and how these insights inform future strategies. The emerging themes focus on technical support and accessibility, training, telehealth specific software and infrastructure, regulatory guidance, increased population access, hybrid trail models, the expansion of AI in telehealth and the expanded use of telehealth in clinical research.

The themes from the project provide best practice guidelines for research organizations. It is recommended that organizations have ongoing access to information technology experts in real-time to avoid delays or significant issues. The real-time access is potentially one of the crucial advantages over having limited technical support. This process can help create a hassle-free experience for both participants and research professionals. Standardized comprehensive training emerged as a best practice. Training for professionals in using telehealth components in clinical research can influence the successful and valid implementation of a clinical trial. On-line training and reference tools are recommended for the initial and on-going education of medical and research professionals. Along similar lines, the project respondents noted the importance of software designed to fit clinical workflows and the ability to be integrated with electronic data capture systems. Best practice guides should provide a review of the telehealth platforms ability to integrate with other required systems for patient enrollment and reporting.

Additional themes emerging from the current project note the benefits of telehealth in increasing access to larger and more diverse populations. It is anticipated that many research designs benefit from reaching individuals in rural and underserved areas and telehealth can be incorporated as a best practice to address this need. This expansion is anticipated to improve the quality and relevance of clinical research findings among a wider range of people.

5.2 Implications for Policy and Practice

One of the themes from the current project pointed out the need for more explicit guidance from regulatory bodies. Respondents would like to receive additional guidance from agencies such as the FDA to embrace telehealth in a wide range of trial procedures. The research in the area of telehealth in clinical trials creates a foundation for polices in organizations that are endorsed by local, state and national agencies. At the organization level, the future of telehealth in clinical trials is dependent on organizations adopting the appropriate platforms, training, and practices to utilize telehealth for many of the components of research. The survey respondents predicted a significant increase in the use of telehealth tools in research but recognized that some organizations are lagging in their implementation.

At the policy and regulatory level, the most significant area of focus is around the IRBs. As noted earlier by Naito and Wills, et al., researchers recommend that IRBs allow for hybrid studies that promote flexibility between in-person and remote visits without a lengthy protocol amendment process. It is further recommended that standardized procedures across IRBs are adopted for clinical research through telehealth (Naito et al., 2021).

Since telehealth licensure requirements vary by state, researchers face challenges in recruiting a diverse population and managing state requirement differences. The IRB rules that the medical licensure requirements of the participant's state of residence must be followed. The role of IRBs is based on federal mandates to review and monitor research with human subjects to protect their well-being and rights during research (Lapid et al., 2019).

As an example of the individual state requirements, the NC Medical Board has ruled on a recent study in North Carolina that providers and researchers using telehealth will be held to the same standards as traditional health in-person settings. The ruling limits the flexibility of the research process and it is recommended that standards involving in-person care should be modified to accommodate the telehealth field. For example, it is unclear when the level of in-person care cannot be met through telehealth. This regulation may create confusion for incorporating telehealth into a research design (NCMB, 2023).

The United States does not have a national IRB system or standardized process. With varying regulations, it is important to implement a national policy standard for telehealth. This change will reduce concerns for researchers in recruiting geographically diverse populations for clinical trials. A national standard would require a review of many complex local regulations and ethical considerations. The effort to establish a national system seems to be a needed policy change to facilitate the expansion of telehealth into clinical research and the inclusion of interstate participants and researchers.

5.3 Limitations

The limitations of the current project include a snowball method to survey distribution, potential self-selection bias, small sample size, and a limited geographic recruitment of the targeted participants in the sample.

The snowball sampling utilized is a non-probability method and may not be fully representative of the target population. This type of sampling also creates a barrier with following up with specific survey participants. Survey formats impacted by self-selection bias and the anonymous nature of the responses makes it impossible to determine why some medical professionals responded and some did not.

The smaller response rate (n=25) is a potential limitation with broad generalization of the results. The recruitment primarily through networking and social media contacts may have some limitations in the reach to the larger medical research community which impacts generalizability.

5.4 Future Research

This project provided insight into the future research related to the role of telehealth in clinical research based on an open-ended question about the utilization over the next five years. The theme of hybrid trail models emerged as a top recommendation from the respondents for future research. The future of clinical research may experience an increase in a combination of approaches between in-person and remote components. The hybrid approach provides a more thorough process for some types of clinical research.

The findings of this survey highlight the optimistic perspective on the contribution of telehealth to clinical research, while also acknowledging the obstacles and opportunities that can arise from the integration of AI. The highest ratings for the use of AI were in automated reminders and check-ins followed by the use of AI in enhancing study designs. There was less support indicated for AI use in automated conversations and addressing barriers in data analysis. The literature review provided support for future of AI in telehealth and clinical research as noted in the work of Palmer, et al (2022) with a younger population participating in a nicotine vaping study that incorporated smartphone apps and similar technology.

The project acknowledges the importance and challenges of AI and technology in telehealth. The respondents noted that a concern about AI algorithm biases and the importance of keeping ethical concerns as a priority. A key area for continued research is the expansion and integration of AI into telehealth models. In prior cancer research, the combination of clinical trials with telehealth and

telemedicine has demonstrated positive utilization in the areas of prevention and reducing risk, screening, diagnosis, treatment, survivorship, and end of life care. As an expanded step, the further implementation of AI into telehealth systems should increase the reach to more candidates and improve the screening process (Von Itzstein et al., 2024).

More recent research has cited the use of AI, such as ChatGPT, into telehealth platforms. These types of AI features have the potential to transform and augment areas of research. However, these researchers noted the importance of transparency, privacy, security, and accountability in the use of AI in clinical research and telehealth. These areas need additional review and research as AI expands in all areas of healthcare and clinical research (Pool et al., 2024).

Future research is needed to support telehealth utilization in clinical trials and set future directions. Researchers conducting multisite clinical trials with telehealth is expanding the reach to broader and more integrated subject populations. The use of telemedicine and telehealth in these designs provide researchers the opportunity to access the results of telehealth and medical intervention in various populations. Continued future research in multisite trails is needed due to the challenges that are not part of traditional clinical trials. There is variability and mixed results in some of the prior research on the efficiency of telehealth in measuring metrics of clinical trials. Areas to be considered in continued research include regulatory and reimbursement issues in integrated telehealth clinical trials, billing and expenses, evaluation of the current standards of the National Institutes of Health and review boards, and the design and implementation of multisite trials (Commiskey et al., 2021).

The results of the project indicate other areas for future research. The use of monitoring and medical devices in telehealth for clinical research was not widely utilized in this project and there are limited examples in the literature review. The combination of devices to measure vital signs, medication levels, and other medical functions could benefit future research.

The need for further study of telehealth devices in research is supported by other studies. While specific treatments need to be delivered in-person during research, the value of the telehealth components

such as intake, monitoring, and follow up provide favorable results. Additional exploration of the expanded use of peripheral medical equipment in clinical trials is recommended for remote evaluation through digital stethoscopes and ultrasound sensors (Daudelin et al., 2022).

Other factors noted as potential challenges to telehealth in clinical research in this project include access to technology and broadband access and participants' comfort levels with technology. It is recommended that additional research focus on funding and training strategies at state and federal levels that address this gap.

Improved cell phone applications may mitigate some of these barriers to telehealth use. It is anticipated that more participants in a clinical study using telehealth will be comfortable and/or have access to mobile technology apps. Future research may involve improving telehealth apps to increase participants' access and comfort levels.

Future research may incorporate additional innovative hybrid designs of telehealth with clinical research. One idea is the use of mobile medical units to reach populations in combination with telehealth services. The use of multiple strategies to reach participants may require expanded educational and awareness campaigns.

5.5 Conclusions

It is predicted that telehealth will continue to transform clinical trials and the research process. This project identified factors and perceptions that foster and hinder the effective use of telehealth in clinical trials and how these insights can inform future strategies and policies to optimize its application. Other research provides support for the improving patient care, increasing access for patients to utilize innovative therapies and medicines, streamlining of data measurements, and increasing communication and research efficiency.

The project supported the expanded use of telehealth in clinical research to improve participant accessibility, diversity and recruitment, provide cost reductions, and have a positive impact on research efficiency. Several limitations of the current project were noted. Future research is recommended with larger sample sizes across a larger national or international region. Future research utilizing AI and

medical devices will add to the advancement of the field of telehealth in clinical research. The policy implications include the standardization of state licensure requirements and consistency in IRBs. To utilize telehealth technology in a way that can truly serve as a major catalyst in the advancement of science, a peer-reviewed and published manuscript on the best practices of telehealth utilization in clinical trials is also needed. Examples include protocol amendments to allow for increased hybrid studies and additional infrastructure support for telehealth tools.

The themes emerging from this project create a framework for understanding how telehealth can transform clinical research. The insights demonstrate a shared vision for a future that prioritizes accessibility, efficiency, and patient-centered care. This vision embraces the potential of technology while also addressing the challenges it presents through careful planning and adherence to regulations. These themes and best practices provide direction for the incorporation of telehealth into clinical trials to enhance efficiency, inclusivity, and patient engagement.

This project provided support for the growth of telehealth in clinical research for the future. The themes in continued expansion and reach were note as the dedication to telehealth is embraced to improved effectiveness and accessibility. Additional research from this project should target the usage and perceptions of telehealth from a larger and more geographically dispersed population to add additional support to the current project findings.

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Appendix A: Survey Template

Survey: An Integrated Review of Telehealth Utilization in Clinical Trials: Facilitators, Barriers, and Future Directions

Survey Instructions

Thank you very much for taking the time to participate in my Doctoral Project at the Medical University of South Carolina. Your insights are invaluable, and the data collected from this survey will play a crucial role in shaping the results and discussion sections of my project, titled "An Integrated Review of Telehealth Utilization in Clinical Trials: Facilitators, Barriers, and Future Directions."

Should you have any questions or require further information, please do not hesitate to contact me at: carpenmi@musc.edu

Privacy and Anonymity
Please be assured that all survey responses are collected anonymously. This means that no information provided can be traced back to individual responders. Your participation is entirely confidential, and the information you share will be used solely for the purposes of this research project.

Thank you again for your valuable contribution!

Section 1: Demographics

Age	_____ (in years)
Professional Role	◯ MD ◯ DO ◯ PA ◯ NP ◯ SW ◯ RPN ◯ Other (Please specify) (Job title)
Other	_____
Years of Experience in the Medical/Research Field	_____ (In years)
Experience with Telehealth	◯ Yes ◯ No
Experience in Clinical Research	◯ Yes ◯ No

How would you assess your proficiency in utilizing Telehealth technologies within clinical research settings?	◯ Novice ◯ Advanced Beginner ◯ Competent ◯ Proficient ◯ Expert

Section 2: In-depth Experience with Telehealth in Clinical Research

Reflecting on your direct involvement, to what extent do you believe telehealth can enhance the efficiency and effectiveness of clinical research trials?	◯ Not at all ◯ Marginally ◯ Moderately ◯ Significantly ◯ Transformative
Based on your experiences, what are the most significant benefits of utilizing telehealth in clinical research? (Select all that apply)	☐ Increased patient accessibility ☐ Cost reduction ☐ Improved data collection efficiency ☐ Enhanced participant diversity ☐ Increased enrollment ☐ Improved equity in participation ☐ Other (Please specify) ((Select all that apply))
Other	_____

Considering your direct experiences over the last three years, how often have telehealth technologies been integrated into your clinical research activities? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
Recruitment Remote	◯	◯	◯	◯	◯
Screening Informed	◯	◯	◯	◯	◯
Consent	◯	◯	◯	◯	◯
Research Treatment/Consulting	◯	◯	◯	◯	◯
Collection of Patient-Reported Outcomes	◯	◯	◯	◯	◯
Use of Wearables or Other Sensors for Remote Monitoring and Compliance	◯	◯	◯	◯	◯
Retention	◯	◯	◯	◯	◯
Follow-Up Visit Via Video Remote	◯	◯	◯	◯	◯
Patient Monitoring	◯	◯	◯	◯	◯

From your perspective, what are the primary challenges or barriers in integrating telehealth into clinical research? (Select all that apply)	☐ Technical issues ☐ Patient privacy concerns ☐ Building patient-researcher rapport ☐ Data reliability and security ☐ Regulatory compliance ☐ Other (Please specify) ((Select all that apply))
Other	_____

Identify any patient or participant barriers you have encountered with telehealth in clinical trials. (Select all that apply)	☐ Cognitive limitations ☐ Aging population needs ☐ Technology access and literacy ☐ Internet accessibility ☐ Language barriers ☐ Geographic location ☐ Other (Please specify) ((Select all that apply))
Other	_____
Which uses of AI in clinical trials and telehealth do anticipate in the future or currently use? (Select all that apply)	☐ Automated conversation or question responses from you participants ☐ Automated reminders and non-human check-ins ☐ Using AI to identify underrepresented study populations ☐ Using AI to enhance trial design ☐ Address barriers in data analysis ☐ Provide real-time monitoring ☐ Other (Please specify) ((Select all that apply))
Other	_____

Section 3: Future Perspectives and Insights

What specific support or resources have you found essential for the successful implementation of telehealth in clinical research? (Please detail based on your experience)
((Open-ended response))

Based on your direct involvement, how do you anticipate the role of telehealth in clinical research evolving over the next five years? (Please share your insights and predictions)
((Open-ended response))

Section 4: Referral Request

We are always looking to gather more perspectives to enrich our research. Do you know of any colleagues, or contacts within the medical or research field who might be interested in participating in this survey on Telehealth Utilization in Clinical Trials? If so, we would greatly appreciate if you could share their email address(es) with us.

We will reach out to them with an invitation to participate, ensuring their participation is voluntary and their responses will be treated with the same confidentiality and anonymity as yours.

- ◯ I am not aware of anyone at this time.
- ◯ I am aware of someone. (Please provide email address(es) below)

Email Address(es):

Appendix B: Survey Results

Results of Survey: An Integrated Review of Telehealth Utilization in Clinical Trials: Facilitators, Barriers, and Future Directions

(NA = No Answer)

Question and Answer Options	N	Percent
Reflecting on your direct involvement, to what extent do you believe telehealth can enhance the efficiency and effectiveness of clinical research trials?		
Moderately	3	12
Significantly	15	60
Transformative	7	28
Based on your experiences, what are the most significant benefits of utilizing telehealth in clinical research? (Select all that apply)		
Increased patient accessibility	22	88
Cost reduction	17	68
Improved data collection efficiency	13	52
Enhanced participant diversity	17	68
Increased enrollment	21	84
Improved equity in participation	18	72
Other	3	12

Considering your direct experiences over the last three years, how often have telehealth technologies been integrated into your clinical research activities? (Select all that apply)

	Never, N (%)	Rarely, N (%)	Sometimes, N (%)	Often, N (%)	Always, N (%)
Recruitment	3 (12)	3 (12)	8 (32)	6 (24)	5 (20)
Remote Screening	1 (4)	5 (20)	8 (32)	9 (36)	2 (8)
Informed Consent	3 (12)	4 (16)	7 (28)	8 (32)	3 (12)
Research Treatment/Consulting	4 (16)	7 (28)	7 (28)	4 (16)	3 (12)
Collection of Patient-Reported Outcomes	3 (12.5)	4 (16.7)	6 (25)	8 (33.3)	3 (12.5)
Use of Wearables or Other Sensors for Remote Monitoring and Compliance	7 (29.2)	6 (25)	6 (25)	4 (16.7)	1 (4.2)
Retention	3 (12)	5 (20)	1 (4)	14 (56)	2 (8)
Follow-Up Visit Via Video	5 (21.7)	1 (4.3)	7 (30.4)	8 (34.8)	2 (8.7)

Remote Patient Monitoring	4 (17.4)	6 (26.1)	4 (17.4)	9 (39.1)	0 (0)
NA = 6					
From your perspective, what are the primary challenges or barriers in integrating telehealth into clinical research? (Select all that apply)					
Technical issues		19		76	
Patient privacy concerns		10		40	
Building patient-researcher rapport		8		32	
Data reliability and security		8		32	
Regulatory compliance		16		64	
Other		2		8	
Identify any patient or participant barriers you have encountered with telehealth in clinical trials. (Select all that apply)					
Cognitive limitations		10		40	
Aging population needs		11		44	
Technology access and literacy		21		84	
Internet accessibility		18		72	
Language barriers		11		44	
Geographic location		6		24	
Other		0		0	
Which uses of AI in clinical trials and telehealth do you anticipate in the future or currently use? (Select all that apply)					
Automated conversation or question responses from participants		9		36	
Automated reminders and non-human check-ins		17		68	
Using AI to identify underrepresented study populations		8		32	
Using AI to enhance trial design		11		44	
Address barriers in data analysis		9		36	
Provide real-time monitoring		11		44	
Other		1		4	